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BONE MINERAL DENSITY 96 WEEKS AFTER ART INITIATION: A RANDOMIZED TRIAL COMPARING EFAVIRENZ-BASED THERAPY WITH A LOPINAVIR/RITONAVIR-CONTAINING REGIMEN WITH SIMPLIFICATION TO LPV/R MONOTHERAPY

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BACKGROUND: Reductions in bone mineral density (BMD) have been described in HIV-infected patients initiating ART. It is unclear whether this is due to an effect of ART or changes in immunologic function or viral activity. We compared changes in BMD from baseline to 96 weeks in subjects randomized to either a lopinavir/ritonavir (LPV/r) simplification strategy or efavirenz (EFV) + zidovudine (ZDV)/lamivudine (3TC). We also sought to identify factors associated with a >5% reduction in BMD.

METHODS: We randomized 155 ART-naïve HIV-1+ subjects (1:2) to receive EFV+ZDV/3TC ($n=51$) or LPV/r+ZDV/3TC induction ($n=104$) for 24 to 48 weeks followed by LPV/r monotherapy (simplification). Subjects were followed for as long as 96 weeks with dual-energy X-ray absorptiometry (DEXA) scans every 24 weeks. Associations between baseline total BMD and other baseline factors were assessed by linear regression. Associations with a 5% decrease in total BMD through 96 weeks were assessed by logistic regression. Factors tested included demographics, weight, HIV-1 RNA, CD4 cell count, smoking/alcohol history, body composition variables, HOMA-IR, tumor necrosis factor (TNF) - α soluble receptors 1 and 2 (sTNFR).

RESULTS: All 74 LPV/r- and 32 EFV-treated subjects had DEXA scans available through 96 weeks. Baseline characteristics, including mean \pm SD total BMD were similar between groups: 1.18 \pm 0.10 g/cm² (LPV/r) and 1.19 \pm 0.12 g/cm² (EFV). In a multivariable analysis, higher baseline BMD was independently associated with higher weight, black race, and higher baseline HIV-1 RNA ($p<0.003$ for each), but was not associated with age, smoking status, use of alcohol, CD4 cell count, or sTNFR. After

96 weeks, mean percentage change from baseline in total BMD was -2.5% (LPV/r) and -2.3% (EFV) ($p < 0.01$ for within-group changes in either arm; $p = 0.86$ for difference between groups). No alteration in the rate of BMD change was observed upon simplification to LPV/r monotherapy. Subjects with lower baseline CD4 cell count, non-black race, and higher baseline fasting glucose demonstrated a higher risk for $>5\%$ decrease in total BMD. Change in total BMD through 96 weeks was not correlated with baseline BMD, others parameters of glucose metabolism, or changes in body composition.

CONCLUSIONS: Similar decreases in total BMD over 96 weeks occurred in ART-naïve subjects receiving either EFV or LPV/r -based regimens, which was not altered by simplification to LPV/r monotherapy. These data suggest that the loss of BMD with ART initiation occurs independently of the ART regimen used. Non-black subjects and those with lower nadir CD4 cell count may be at increased risk of more pronounced BMD loss.

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