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24-WEEK EFFICACY AND SAFETY OF NEVIRAPINE: 400 MG VERSUS 600 MG BASED HAART IN HIV-INFECTED PATIENTS WITH ACTIVE TUBERCULOSIS RECEIVING RIFAMPICIN

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OBJECTIVES: Nevirapine (NVP) fixed dose combinations are widely used in resource limited settings where the tuberculosis (TB) burden is high. This study was to determine the appropriate dose of NVP in HIV/TB co-infected patients receiving RIF.

METHODS: 32 HIV-TB co-infected adults (16 per arm) with CD4 < 200 cells/ μ L and active TB, receiving RIF 2-6 weeks were randomized to receive NVP 400 (NVP400) or 600 mg (NVP600) per day plus 2NRTIs. A NVP lead-in was performed at 200 mg QD (NVP400) and 200 mg BID (NVP600) for 2 weeks. Plasma NVP levels were obtained at week 2, 4, and 12 by HPLC.

RESULTS: Baseline characteristics were comparable among two groups. Median NVP C_{min} levels at week 2 were significantly lower in NVP400 (1.9 vs 4.83, $p=0.001$). There were more cases of NVP C_{min} levels < 3.1 mg/L at week 2 in NVP400 (79% vs 19%, $p=0.002$). However, NVP C_{min} was comparable at week 4 (4.05 vs 5.84, $p=0.06$) and week 12 (4.27 vs 5.53, $p=0.24$). NVP600 had a higher trend to NVP hypersensitivity (31 vs 6%, $p=0.07$) and study discontinuation (44 vs 25%, $p=0.23$). Two HIV/HCV (NVP600) and 1 HIV/HBV patients (NVP400) had grade-2 ALT elevation. The 24-week efficacy showed no difference in the proportion with HIV RNA < 50c/mL (62 vs 50 % by ITT; $p=0.49$, and 83 vs 89% by OT) and the median (IQR) CD4 rise [106 (63.5-172.5) vs 44 (34.5-101) $p=0.07$].

CONCLUSIONS: A high percentage of suboptimal levels were found in the 200 mg qd lead-in period whereas the NVP 200mg BID lead in was associated with drug hypersensitivity. However, NVP dosed at 200mg BID as part of combination ART with 200 mg qd lead-in provided potent virological suppression and good CD4 response over 24 weeks observation. NVP 200 mg BID should be sufficient for most Thai HIV-infected patients receiving RIF.



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TB / HIV: Still a Deadly Partnership

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