



# 1st International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV

26–28 June 1999 - San Diego, CA, USA

## SAFETY AND TOLERABILITY OF ANTIRETROVIRAL THERAPY IN THE BRITISH COLUMBIA DRUG TREATMENT PROGRAM

*Antiviral Therapy* 1999; 4(Suppl. 2):61(abstract no. 50)

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**OBJECTIVE:** To assess the safety and tolerability of antiretroviral therapy (ARV) in participants enrolled in an HIV/AIDS treatment programme.

**DESIGN:** In British Columbia, antiretroviral therapies are distributed free of charge according to specific therapeutic guidelines. Study subjects were ARV-naïve and started triple combination therapy (two NRTIs with a PI or a NNRTI) between July 1996 and May 1998. Each participant had baseline haemoglobin and at least one post-therapy haemoglobin result available. Anaemia is defined as haemoglobin <123 g/l for females and <140 g/l for males. Virological response is defined as having at least two consecutive post-therapy plasma viral load (pVL) <500 copies/ml. Statistical comparisons were conducted using distribution-free and multivariate logistic methods.

**RESULTS:** A total of 301 subjects (290 males/11 females) were studied. Their median age was 38 (IQR 33–44 years) with median baseline pVL of 130,000 copies/ml (IQR 62,000–300,000 copies/ml). Anaemia was seen in 41% (122) of the 301 participants after starting ARV. The anaemic group had a higher proportion of patients previously exposed to zidovudine (49% versus 32%;  $P=0.003$ ), a lower virological response rate (59% versus 78%;  $P=0.001$ ) and a higher proportion of injection drug users (IDU) (25% versus 12%;  $P=0.003$ ) in comparison to the non-anaemic group. There was no difference between the two groups with respect to baseline age, pVL and CD4 cell count. When controlling for baseline haemoglobin level and follow-up time in a multivariate logistic model, the use of zidovudine (odds ratio=2.83;  $P<0.001$ ), having poorer virological response (odds ratio=0.50;  $P=0.016$ ) and IDU (odds ratio=2.23;  $P=0.021$ ) were associated with having anaemia post ARV.

**CONCLUSION:** As more effective ARV becomes available, safety and tolerability of treatment is becoming of increasing importance. Although some antiretroviral agents may be associated with detrimental effects, such as anaemia, the overall benefit of effective therapy may be protective.

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