

Clinical Efficacy and Effectiveness of Antiretroviral Therapy in Treatment Naïve Women. Nevert Badreldin, Jennifer Wall-Forrester, Jennifer Calder, and Carl J. Fichtenbaum.

BACKGROUND: It is not clear whether the efficacy achieved in clinical trials translates into clinical effectiveness in practice. The aims of this study were to compare the initial efficacy and long-term durability of combination antiretroviral treatment in antiretroviral-naïve HIV-infected women compared to men and in women treated in clinical practice versus those enrolled in clinical studies. We hypothesized that there would be little difference in outcomes between men and women. Furthermore, there would be no difference in outcomes between women enrolled in clinical trials compared to those treated in clinical practice.

METHODS: A retrospective review of medical records of treatment-naïve HIV-infected persons initiating combination antiretroviral therapy between 1996 and 2009. The primary endpoint was the proportion of individuals with an undetectable HIV viral load at time of last follow-up. Secondary endpoints included the initial treatment response by 8 months on the first treatment regimen, immunologic success, and clinical outcomes.

RESULTS: There were 543 patients included in the study: 26% women and 74% were men. 62% of women were Black or African compared to 43% of men ($P=0.002$). Durable treatment responses (HIV viral load < 400 copies/mL) were similar in men and women at the time of last follow-up (60% vs. 54%, respectively, $P=0.18$). Initial successful treatment responses (HIV viral load < 400 copies/mL) were observed in 64% of men versus 62% of women ($P=NS$). There were significant differences in the type of initial antiretroviral regimens ($P=0.005$). Women had higher initial CD4 counts (249 vs. 187 cells/mm³, $P=0.002$), and lower HIV viral loads (47,800 vs. 89,266 copies/mL, $P<0.001$) at time of presentation. Adverse events were similar in women and men (41% vs. 38%, respectively, $P=NS$). Analysis of data for clinical trials versus clinical practice is ongoing.

CONCLUSION: Treatment outcomes for women and men appear to be similar overall despite women generally presenting earlier in the course of their HIV illness. More than 50% of individuals on antiretroviral therapy are able to achieve long-term suppression of HIV replication.