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Long-Term Nevirapine Safe and Effective in Treating HIV, With No Deterioration of Lipid Profile: Presented at ECCMID

By Chris Berrie

VIENNA, Austria -- April 12, 2010 -- Long-term nevirapine (NVP)-based highly active antiretroviral therapy (HAART) is safe and effective for patients infected with HIV, with no deterioration seen in subjects' lipid profiles, according to a retrospective study presented at the 20th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID).

The combination of protease inhibitors (PIs) with HAART -- a mainstay of treatment for patients with HIV infection -- is commonly associated with hypercholesterolaemia and hypertriglyceridaemia. The use of NVP, however, has provided a therapy with limited adverse effects on patients' lipid profiles, noted principal investigator Cristina Hidalgo, MD, Infectious Diseases Division, Fundación Jiménez Diaz, Madrid, Spain, speaking here on April 11.

All studies of NVP-based HAART have been short term to date, explained Dr. Hidalgo. With this observational, longitudinal study, she stated, "We have studied for 10 years the development of the side effects and efficacy of the clinical and virological evolution of the patients."

The 107 subjects in this study (mean age of 34.8 years; 81% male) began NVP-based HAART as either first-line therapy (12.1%) or following PI-based treatments as a therapy-switching strategy with undetectable viral load (75.7%) or because of previous treatment failure (12.1%). The HIV infection had been acquired through either sexual (82.2%) or parenteral (17.8%) routes.

Baseline characteristics included a mean CD4+ nadir of 266.5 cells/mcL, and a mean CD4+ cell count of 549 cells/mcL at NVP initiation.

For the 81 patients receiving NVP for therapy switching, the causes of the switch were voluntary simplification (58.0%), lipodystrophy (19.7%), hypercholesterolaemia and/or hypertriglyceridaemia (7.4%), and other toxicities (14.8%).

NVP treatment was introduced at 200 mg once daily, and then raised to 200 mg twice daily. After 132 months of follow-up, the subjects' mean time on NVP-based HAART was 63 months, with 43 patients (40.1%) still on therapy with undetectable viral load after a mean of

104 months of follow-up. Eight subjects (7.5%) developed Kaposi's sarcoma, and 3 subjects (2.8%) died due to non-AIDS-defining complications.

The discontinuation of NVP therapy in 64 patients was due to structured treatment discontinuation (42.2%), virologic failure (21.9%), toxicity (17.2%), change in treatment strategy (9.4%), and unknown reasons (9.4%).

The subjects' mean CD4+ cell counts increased by 139 cells/mcL, while for metabolic abnormalities, with the 26 patients (24.3%) with baseline serum cholesterol >240 mg/dL (mean, 278 mg/dL), this significantly decreased to 248 mg/dL ($P < .05$) at the end of follow-up. Similarly, with the 8 patients (7.5%) with baseline serum triglycerides >400 mg/dL (mean, 972 mg/dL), this significantly decreased to 521 mg/dL ($P < .05$) at the end of follow-up.

Dr. Hidalgo's team concluded that, while remaining an effective and safe long-term treatment for these patients, NVP-based HAART demonstrated no deterioration in the lipid profile over time, with overall no change in mean serum cholesterol levels and decreased triglyceride levels to the end of follow-up.

Stated Dr. Hidalgo, "Nevirapine does not have side effects on lipids, cholesterol and triglycerides as the other drugs do. It is safe, and you can use it for a long time ... and we have better results with nevirapine than with protease inhibitors."

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