Outcomes of Patients Switched from Enfuvirtide (ENF) to Raltegravir (RAL) within a Virologically Suppressive Regimen

M Harris, G Larsen, J Montaner
British Columbia Centre for Excellence in HIV/AIDS
Providence Health Care/St. Paul’s Hospital, Vancouver, B.C., Canada

METHODS

Patients
All patients at a single clinic (Immune Deficiency Clinic, St. Paul’s Hospital, Vancouver, BC, Canada) with
• Plasma viral load (VL) <50 copies/mL, and
• treatment-limiting injection site reactions (ISR) on an ENF-containing regimen
were offered a switch from ENF to RAL.

Drug treatment
• ENF discontinued
• RAL 400 mg orally twice daily started
• Remainder of antiretroviral (ARV) regimen unchanged
• RAL was obtained through the Special Access Program of Health Canada.
• RAL was started between November 20, 2006 and October 19, 2007.

Evaluations
Patients were followed according to standard clinical practice, including:
• Plasma viral load (VL)
• CD4 cell counts, absolute and %
• adverse events
• ARV drug discontinuations

Follow-up results are presented up to January 10, 2008.

BACKGROUND
The fusion inhibitor enfuvirtide (ENF) has been a successful cornerstone of salvage therapy for patients with multidrug-resistant HIV. The integrase inhibitor raltegravir (RAL) provides another option for a novel drug class, with the advantages of easier administration and improved tolerability.

RESULTS

Virologic outcomes (Figure 1)
• 34/35 patients have VL <50 copies/mL at the most recent follow-up.
• The remaining patient had VL <50 copies/mL at 1 and 2 months, and 60 copies/mL at 5 months after starting RAL.
• Median follow-up time is 7 months (range 1 to 13 months) after stopping ENF and starting RAL.
• No patients restarted ENF.

Adverse event outcomes
ISR-related problems resolved in all patients.
The following adverse events were observed, each in one patient:
• Peripheral neuropathy and diarrhea (after 1 month on RAL)
• Exacerbation of depression (after 1 month on RAL)
• Pneumonia (2 episodes)
• Prostate cancer (in a 56-year old man after 1 month on RAL)
• B-cell lymphoma (in a 52-year old man after 9 months on RAL)

None of these events was considered related to RAL.
No new laboratory abnormalities were identified.
No patients discontinued RAL.

CONCLUSIONS
Changing from ENF to RAL within a virologically suppressive regimen appears to be safe and effective over the short term (median 7 months) among patients with multidrug-resistant HIV.

Figure 1a
Time on RAL at latest follow-up

Figure 1b
Viral load (VL) at latest follow-up