



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

Dr. M. Harris
Rm. 667-1081 Bernard St.
Vancouver, B.C. V6Z 1Y6
Tel. (604) 806-8771 Fax. (604) 806-8412
Email: mharris@cfe.ubc.ca



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.

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.

RESULTS

Baseline characteristics

	male	female
Gender, N	34	1
	median	range
Age, years	49	34-69
Time on ENF before switch, months	25	5-75
Time VL <50 copies/mL before switch, months	24	1-72
CD4 count, cells/mm ³	350	90-770
CD4 fraction, %	16%	4-43%
Concomitant ARVs, N		
NRTI/NRTI ^{II}	3	1-4
NNRTI ^{II}	0	0-1
PI ^{II}	1	1-2

* efavirenz n=3 efavirenz n=2 nevirapine n=1
** Ritonavir-boosted in 33/35

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.

Figure 1a
Time on RAL at latest follow-up

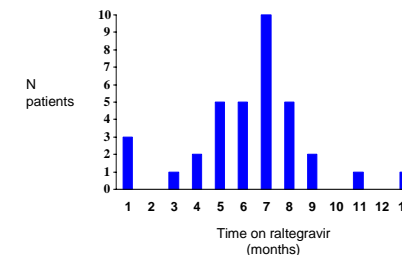
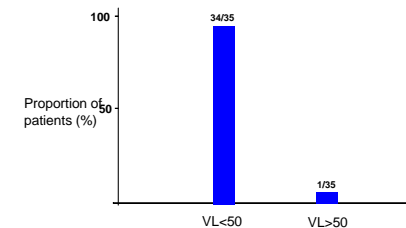


Figure 1b
Viral load (VL) at latest follow-up



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.