

Analysis of a Switch From Enfuvirtide to Raltegravir in Patients With Undetectable Viral Load: Efficacy and Quality of Life at 24 Weeks

To the Editor:

Tolerability and potential for long-term treatment adherence are critical components of a successful human immunodeficiency virus (HIV) treatment regimen. Approval of newer classes of antiretroviral (ARV) medications allows new options for HIV-infected patients. Enfuvirtide (ENF) is a potent ARV medication dosed subcutaneously twice daily in treatment-experienced HIV-infected patients. In clinical trials, nearly all ENF-treated patients (97.6%) had at least 1 injection-site reaction.¹ A total of 11 patients (3.3%) in the ENF group and 3 patients in the control group who switched to ENF (2.6%) discontinued treatment with ENF owing to injection-site reactions.¹ Other difficulties reported were dislike of self-injection and storage of needles and injection paraphernalia.²

Raltegravir (RAL) is the first in a new class of integrase inhibitors that was approved by the US Food and Drug Administration (FDA) for use in treatment-experienced adult patients who have evidence of viral replication and HIV strains resistant to multiple ARV drugs. It has demonstrated potent efficacy through 48 weeks in 2 controlled studies that were conducted in clinically advanced, 3-class ARV medication, treatment-experienced adults.³

We conducted a study to assess the virologic and quality of life effects of changing ENF to RAL in HIV-infected patients with an undetectable viral load, defined as HIV-RNA levels <50 copies/mL. This was a multicenter, open label, historical controlled study, which included patients from 6 AIDS Healthcare Foundation's Clinics in California. Patients who were 18 years or older, who were receiving a stable ARV regimen containing ENF for

>6 months, with HIV-RNA levels <50 copies/mL and no previous use of RAL or elvitegravir were asked to participate. Patients who were willing had their ARV medication changed from ENF to RAL with no other ARV medication change. Human immunodeficiency virus-1 RNA measurements and CD4 counts were performed at baseline, week 12, and week 24. A quality of life questionnaire was administered at week 12.

A total of 25 patients met our inclusion criteria (24 men and 1 woman). The mean age was 49 years (range 33-64). The baseline CD4 count was 332 cells/mm³ (range 155-538). In all, 60% (15) of patients completed the quality of life questionnaire whose results are summarized in Table 1.

All the patients (22/22) who were followed at 6 months maintained an HIV-RNA level <48 copies/mL and an average CD4 count of 370 cells/mm³ (range 211-700). In all, 2 patients were lost to follow up and 1 died from head trauma.

Few prior studies have shown the virologic effect of switching ENF to RAL in virologically suppressed patients. One study showed all 35 patients having maintained undetectable viral loads for several months.⁴ In another report, 18 participants on ENF for a median of 21 months discontinued this agent in favor of RAL and all maintained virologic suppression for more than 12 weeks.⁵ A larger study showed that 94% of 52 patients were able to maintain viral suppression at 12 weeks and their CD4 counts increased by an average of +32 cells/mm³.⁶

In summary, our findings show that a switch from ENF to RAL in virologically suppressed patients who are highly treatment-experienced maintain both virologic and immunologic efficacy up to 24 weeks.

Table 1. Summary of Quality of Life Questionnaire

Question	% That Answered Yes
ENF is very difficult to inject	53
ENF interferes with activities and sports	79
RAL improves the ability to participate in activities and sports	79
ENF limits the ability to maintain privacy about HIV status	60
RAL had little or no effect on maintaining privacy about HIV status	93
ENF in some way limited the ability to travel away from home	87
RAL did not limit the ability to travel away from home	93
The switch from ENF to RAL improved their quality of life	93

Abbreviations: ENF, enfuvirtide; HIV, human immunodeficiency virus; RAL, raltegravir.

In addition, this switch allows significant improvement in quality of life in this population.

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