Antiretroviral Therapy (ART) in Clinical Practice: Effectiveness and Tolerability of Nevirapine (NVP), Stavudine (d4T) and Lamivudine (3TC)

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ANTIRETROVIRAL THERAPY (ART) IN CLINICAL PRACTICE: EFFECTIVENESS AND TOLERABILITY OF NEVIRAPINE (NVP), STAVUDINE (d4T), AND LAMIVUDINE (3TC)

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ABSTRACT

Background: Recent studies reveal that viral suppression in clinical practice is achieved less frequently than in clinical trials. This study examines the effectiveness and tolerability of an NVP/d4T/3TC ART regimen in an urban HIV clinic. Methods: A retrospective review of patients (N = 536) from 9/96 to 4/00 yielded 73 patients on NVP/d4T/3TC. Retrospective data demographics, viral load (VL), CD4+ cell count, previous regimen, adverse events (AEs), and reasons for discontinuation were collected. Results: Study patients were similar to previous clinical studies. 12/24 were HAART-naive. Common reasons for choosing NVP/d4T/3TC included: VL, absence of PI-associated DRs, and low pill burden. Intent-To-Treat (ITT) Week 16: 57/73 (78%) had VL <100K. Week 24: 39/73 (53%) had VL <40K. AT Week 16: 19/73 patients had VL <40K. At 16 weeks, 39/73 patients had VL <100K. At 24 weeks, 34/73 patients had VL <100K. Mean CD4+ increase at 16 weeks was 70 (95% CI: 120, 219). Discontinuance rates (6%) were similar to or better than what would be expected based on previous studies of other NVP-containing regimens. Conclusions: Despite a general barrier, NVP/d4T/3TC is effective and tolerable. Viral suppression was higher than expected in an urban clinic. There was low discontinuation due to rash or virologic failure in the first 24 weeks. The low pill burden, ease of administration, and lack of AEs make this regimen suitable and effective in clinical practice.

BACKGROUND

In clinical practice, patients on protease inhibitor (PI)-based regimens achieve viral suppression less frequently than in randomized, double-blinded, placebo-controlled clinical trials.1-4 Many factors influence this discrepancy, including adherence and the use of HAART in heavily antiretroviral-experienced patients. To avoid the complex dosing schedules and side effects of PI therapy, the non-nucleoside reverse transcriptase inhibitor (NNRTI) nevirapine (NVP) has been used as an alternative in patients with low baseline viral loads (VLs). Recent data suggest that the efficacy of NVP-based regimens in patients with a VL greater than 100,000 copies/mL may be sufficient to result in long-term viral suppression.5-11 The most common side effects of NNRTI-based regimens are cutaneous, neurologic, gastrointestinal (GI), and hematologic. This study examines the efficacy of NVP/d4T/3TC in a patient population in an urban HIV clinic.

METHODS

Patients included all patients seen from 9/96 to 4/00 who were receiving NVP/d4T/3TC. Retrospective data were collected on demographics, viral load (VL), CD4+ cell count, previous regimen, adverse events (AEs), and reasons for discontinuation. Common reasons for choosing NVP/d4T/3TC included: VL, absence of PI-associated DRs, and low pill burden. Intent-To-Treat (ITT) Week 16: 57/73 (78%) had VL <100K. Week 24: 39/73 (53%) had VL <40K. AT Week 16: 19/73 patients had VL <40K. At 16 weeks, 39/73 patients had VL <100K. Mean CD4+ increase at 16 weeks was 70 (95% CI: 120, 219). Discontinuance rates (6%) were similar to or better than what would be expected based on previous studies of other NVP-containing regimens. Conclusions: Despite a general barrier, NVP/d4T/3TC is effective and tolerable. Viral suppression was higher than expected in an urban clinic. There was low discontinuation due to rash or virologic failure in the first 24 weeks. The low pill burden, ease of administration, and lack of AEs make this regimen suitable and effective in clinical practice.