Follow-up data was provided on a voluntary basis for HIV-RNA, CD4 and Serious Adverse Events. Agreement with the Drug Agency to an “ATU” program (“Autorisation Temporaire d’Utilisation”, Provisional Authorization for Use) between March 2000 and April 2001. A total of 3,447 patients were included in this summary. The mean baseline HIV RNA and CD4 count for these patients were 4.66 log10 copies/mL and 202 cells/mm3, respectively. Two hundred fifty-two new opportunistic infections occurred in 135/1,846 (7.3%) patients for whom information was available during the three-month period prior to the NRTI therapy starting.

METHODS

Summary of Baseline Demographic and Disease Characteristics

A total of 1,347 patients were included in this summary. The mean baseline HIV RNA and CD4 count for these patients were 4.66 log10 copies/mL and 202 cells/mm3, respectively. Ninety percent of patients were younger than 50 years of age. The majority of patients were male (80%) and were 35-40 years of age (30%). The median age of patients was 40 years, with the single most highly represented group being 20-24 years of age (47%). The median of 1990-1994 was 41.4%, and the median of 1995-2000 was 29%.

RESULTS

Prior Antiretroviral Experience

As the selection criteria became less restrictive, the mean baseline status of the patient population shifted to healthier patients, as reflected by Figures 5 and 6. Prior antiretroviral experience for these patients is provided in Figures 8 and 9. The majority of patients (86%) received two or more previous ART regimens. A total of 152/3,447 (4.4%) patients prior to LPV/r therapy were on a protease inhibitor (PI) monotherapy. Concomitant NRTI use in the PI-containing regimens for the study population are provided in Figure 13 and 14. The majority of patients (58%) received two NRTIs and one PI, or two categories of PI drugs, LPV/r and/or RTV.

Concomitant Antiretroviral Therapy

Concomitant use of another PI was uncommon in this population. Ninety percent of patients received more than three concomitant ARVs. Concomitant use of another PI was uncommon in this population.

Mean Baseline Viral Load

The mean baseline viral load was 3,333 copies/mL, with 98% of patients having a viral load greater than 1,000 copies/mL. The median baseline viral load was 2,000 copies/mL. The median of 1990-1994 was 3,333 copies/mL, and the median of 1995-2000 was 2,000 copies/mL.

Mean Baseline CD4 Cell Count

The mean baseline CD4 cell count was 202 cells/mm3, with 80% of patients having a CD4 cell count greater than 100 cells/mm3. The median baseline CD4 cell count was 202 cells/mm3. The median of 1990-1994 was 202 cells/mm3, and the median of 1995-2000 was 202 cells/mm3.

Baseline Genotype

Approximately half of the patients (777/1,604, 48%) had a baseline LPV/r phenotype associated with reduced susceptibility to LPV. The majority of patients (67%) received two or more primary mutations in positions 50, 53, and/or 63, as well as secondary mutations at positions 2, 5, 9, and/or 13. The baseline LPV median number of mutations associated with reduced susceptibility to LPV was 11 (range 1-50) (N = 1828). The majority of patients had a baseline LPV mutation score of 1 or 2 mutations (Figure 10).

Concomitant NRTIs

Concomitant NRTIs in the LPV/r-containing regimen for the study population are provided in Figures 13 and 14. The majority of patients (86%) received two or more NRTIs. Concomitant use of NRTIs in the PI-containing regimen for the study population is provided in Figures 13 and 14. The majority of patients (86%) received two or more NRTIs. Concomitant use of NRTIs in the PI-containing regimen for the study population is provided in Figures 13 and 14.

C O N C L U S I O N S

With 50% of patients in the US who are age 50 or older benefit from HIV therapy and the reduction in the age of the HIV population to age 30, this new treatment regimen may improve the quality of life for these patients. The mean baseline viral load was 3,333 copies/mL, with 98% of patients having a viral load greater than 1,000 copies/mL. The majority of patients (86%) received two or more previous ART regimens. The median baseline viral load was 2,000 copies/mL. The median of 1990-1994 was 3,333 copies/mL, and the median of 1995-2000 was 2,000 copies/mL.

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