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Abacavir–Lamivudine versus Tenofovir–Emtricitabine for Initial HIV-1 Therapy

Paul E. Sax, M.D., Camlin Tierney, Ph.D., Ann C. Collier, M.D., Margaret A. Fischl, M.D., Katie Mollan, M.S., Lynne Peeples, M.S., Catherine Godfrey, M.D., Nasreen C. Jahed, M.P.H., Laurie Myers, M.S., David Katzenstein, M.D., Awny Farajallah, M.D., James F. Rooney, M.D., Belinda Ha, Ph.D., William C. Woodward, M.D., Susan L. Koletar, M.D., Victoria A. Johnson, M.D., P. Jan Geiseler, M.D., Eric S. Daar, M.D., for the AIDS Clinical Trials Group Study A5202 Team

ABSTRACT

Background The use of fixed-dose combination nucleoside reverse-transcriptase inhibitors (NRTIs) with a nonnucleoside reverse-transcriptase inhibitor or a ritonavir-boosted protease inhibitor is recommended as initial therapy in patients with human immunodeficiency virus type 1 (HIV-1) infection, but which NRTI combination has greater efficacy and safety is not known.

Methods In a randomized, blinded equivalence study involving 1858 eligible patients, we compared four once-daily antiretroviral regimens as initial therapy for HIV-1 infection: abacavir–lamivudine or tenofovir disoproxil fumarate (DF)–emtricitabine plus efavirenz or ritonavir-boosted atazanavir. The primary efficacy end point was the time from randomization to virologic failure (defined as a confirmed HIV-1 RNA level ≥ 1000 copies per milliliter at or after 16 weeks and before 24 weeks, or ≥ 200 copies per milliliter at or after 24 weeks).

Results A scheduled interim review by an independent data and safety monitoring board showed significant differences in virologic efficacy, according to the NRTI combination, among patients with screening HIV-1 RNA levels of 100,000 copies per milliliter or more. At a median follow-up of 60 weeks, among the 797 patients with screening HIV-1 RNA levels of 100,000 copies per milliliter or more, the time to virologic failure was significantly shorter in the abacavir–lamivudine group than in the tenofovir DF–emtricitabine group (hazard ratio, 2.33; 95% confidence interval, 1.46 to 3.72; $P < 0.001$), with 57 virologic failures (14%) in the abacavir–lamivudine group versus 26 (7%) in the tenofovir DF–emtricitabine group. The time to the first adverse event was also shorter in the abacavir–lamivudine group ($P < 0.001$). There was no significant difference between the study groups in the change from the baseline CD4 cell count at week 48.

Conclusions In patients with screening HIV-1 RNA levels of 100,000 copies per milliliter or more, the times to virologic failure and the first adverse event were both significantly shorter in patients randomly assigned to abacavir–lamivudine than in those assigned to tenofovir DF–emtricitabine. (ClinicalTrials.gov number, NCT00118898 [ClinicalTrials.gov] .)

Source Information

From the Division of Infectious Diseases and the Department of Medicine, Brigham and Women's Hospital and Harvard Medical School (P.E.S.), and the Harvard School of Public Health (C.T., K.M., L.P.) — all in Boston; the University of Washington and Harborview Medical Center, Seattle (A.C.C.); the University of Miami School of Medicine, Miami (M.A.F.); the Division of AIDS, National Institute of Allergy and Infectious Diseases, Bethesda (C.G.), and Social and Scientific Systems, Silver Spring (N.C.J.) — both in Maryland; Frontier Science and Technology Research Foundation, Amherst, NY (L.M.); Stanford University,

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Palo Alto (D.K.), Gilead Sciences, Foster City (J.F.R.), University of Southern California, Los Angeles (P.J.G.), and Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center and the University of California, Los Angeles (E.S.D.) — all in California; Bristol-Myers Squibb, Plainsboro, NJ (A.F.); GlaxoSmithKline, Research Triangle Park, NC (B.H.); Abbott Laboratories, Abbott Park, IL (W.C.W.); Ohio State University, Columbus (S.L.K.); and the Birmingham Veterans Affairs Medical Center and University of Alabama School of Medicine at Birmingham, Birmingham (V.A.J.).

Address reprint requests to Dr. Sax at Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, or at psax@partners.org.

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