Quality-of-life evaluation in a clinical trial of zidovudine therapy in patients with mildly symptomatic HIV infection. The AIDS Clinical Trials Group.

Gelber RD, Lenderking WR, Cotton DJ, Cole BF, Fischl MA, Goldhirsch A, Testa MA.

Division of Biostatistics and Epidemiology, Dana-Farber Cancer Institute, Boston, MA 02115.

Abstract

OBJECTIVE: To evaluate the effects of zidovudine therapy in patients with mildly symptomatic HIV infection using Q-TWiST (quality-adjusted: Time Without Symptoms and Toxicity).

DESIGN: Analysis of a previously reported multicenter, randomized, placebo-controlled clinical trial.

SETTING: Thirty-two AIDS Clinical Trial units.

PATIENTS: A total of 351 patients with mildly symptomatic HIV infection were assigned to placebo, and 360 patients were assigned to zidovudine, 1200 mg/d.

MEASUREMENTS: A modified Q-TWiST method for comparing treatments based on time spent without severe symptomatic adverse events and without disease progression. Zidovudine and placebo were compared in a threshold utility analysis considering reduction in quality of life associated with adverse events and disease progression. Adverse events defined by laboratory findings were distinguished from findings representing symptomatic events.

RESULTS: The incidence of severe symptomatic adverse events was 22.8% for the zidovudine group and 15.1% for the placebo group (P = 0.01), but, as previously reported, zidovudine improved progression-free survival relative to placebo (at 18 months, 91% compared with 81%; P = 0.001). In an 18-month period, patients receiving zidovudine went an average of 14.5 months without disease progression or a severe symptomatic adverse event compared with 14.7 months for placebo. The zidovudine group gained 0.9 months without disease progression but lost 1.1 months due to adverse events. Within the 18-month observation period, treatment provided more Q-TWiST than placebo if the quality of life after HIV disease progression was assumed to be 10% to 20% worse than the quality of life after a severe symptomatic adverse event.

CONCLUSIONS: The Q-TWiST analysis projects that quality-of-life reductions due to severe symptomatic adverse events might be balanced by the quality-of-life benefits of delayed HIV disease progression for patients who received zidovudine for mildly symptomatic HIV infection. At currently recommended doses (500 to 600 mg/d, half the dose used in this study) zidovudine therapy is likely to yield a more favorable result.

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