Quality of life in a placebo-controlled trial of zidovudine in patients with AIDS and AIDS-related complex.

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Abstract

We measured quality of life using the Karnofsky Performance Status and Quality of Well-Being scale (QWB) for 31 patients with AIDS and AIDS-related complex in a placebo-controlled trial of zidovudine. Sixteen patients were randomized to zidovudine and 15 to placebo. We recorded nine scores for each patient during 1 year. During the blinded trial, 3 patients receiving placebo died; at 1 year, one had died in the zidovudine group and 10 in the placebo group. Repeated-measures analysis of variance demonstrated that mean scores declined less for the zidovudine group than for the placebo group during the blinded trial (p less than 0.03) and during 1 year (p less than 0.002). However, because the QWB incorporates death into its score, these results largely reflected differences in mortality. When data from those who died were excluded, Karnofsky scores were higher for the zidovudine group at the end of the blinded trial (p less than 0.02), but at 1 year no significant differences were observed between groups. The QWB and other quality-of-life measures may contribute to more comprehensive evaluation of AIDS treatments, and may detect treatment effects earlier. Whether existing measures can detect real differences among survivors will require testing in patients with less advanced disease.

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