Comparison of health-related quality of life in clinical trial and nonclinical trial human immunodeficiency virus-infected cohorts.

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Abstract

Clinical trials randomly assign treatments and select participants to maximize internal validity, but such selection threatens generalizability by excluding important groups with the diseases under study. Particularly in human immunodeficiency virus (HIV) disease, the results of clinical trials are applied broadly to populations, despite limited representation by minorities and disadvantaged groups. Health-related quality of life (HRQOL), which is increasingly recognized as an important outcome in these studies, may be sensitive to differences that affect generalization of trial results to target populations. This study compared HRQOL in two HIV-infected cohorts: 1) multicenter AIDS Clinical Group Trials in which most subjects are white, privately insured, and high-income (n = 1,907); and 2) a study of ethnically diverse, low-income patients recruited from public clinics (n = 205). Both studies included 30 HRQOL items developed in the Medical Outcomes Study (MOS) and items on symptoms, medications, and demographic characteristics. HRQOL scores were significantly lower in the nontrial sample (P < 0.001) by about one standard deviation, even after direct adjustment for clinical and demographic characteristics, and also after comparison of the nontrial sample with the most symptomatic in the trial sample. The relationships of characteristics with HRQOL differed between nontrial and trial samples, suggesting problems generalizing results from HIV clinical trials to important target populations. HRQOL measures such as those from the MOS can be useful in detecting differences that affect generalization.