

# Quality-of-life measures improved in a mild hypertension study

Grimm RH Jr, Grandits GA, Cutler JA, et al., for the TOMHS Research Group. **Relationships of quality-of-life measures to long-term lifestyle and drug treatment in the Treatment of Mild Hypertension Study.** Arch Intern Med. 1997 Mar 24; 157:638-48.

## Objective

To assess quality-of-life (QOL) measures in patients enrolled in a trial of 5 classes of antihypertensive drugs for mild diastolic hypertension.

## Design

4-year randomized, double-blind, placebo-controlled trial.

## Setting

{4 clinical research units in the United States.}\*

## Patients

902 patients (mean age 55 y, 62% men) who had stage I diastolic hypertension (diastolic blood pressure 90 to 99 mm Hg) and no cardiovascular disease (CVD). Follow-up was 87% at 4 years.

## Intervention

All patients received intensive counseling aimed at weight loss, decreased sodium and alcohol intake, and increased physical activity. Patients were allocated to placebo ( $n = 234$ ) or 1 of 5 antihyper-

*Commentary*  
Controversy exists about whether the benefits of treatment for "mild" hypertension exceed the risk associated with pharmacologic therapy and whether nonpharmacologic approaches yield better results (1). A component of the controversy is whether QOL is adversely affected in drug-treated patients.

The study by Grimm and colleagues examines QOL issues in patients receiving various forms of drug therapy, including placebo. The operating characteristics of the QOL indexes seem to be sound (2). The most striking feature of this study is the positive QOL changes over time for all pharmacologic treatment groups compared with placebo, especially with acebutolol and chlorthalidone.

All patients showed improvement in QOL,

tensive drugs: acebutolol, 400 mg/d ( $n = 132$ ); amlodipine, 5 mg/d ( $n = 131$ ); chlorthalidone, 15 mg/d ( $n = 136$ ); doxazosin, 2 mg/d ( $n = 134$ ); or enalapril, 5 mg/d ( $n = 135$ ). If diastolic blood pressure remained elevated, drug doses were doubled and finally chlorthalidone (or enalapril if patients were assigned to chlorthalidone) was added.

## Main outcome measures

A validated, 35-item QOL questionnaire was given at baseline, 3 months, and annually. 7 QOL indexes were calculated: general health perceptions, energy or fatigue, mental health, general functioning, satisfaction with physical abilities, social functioning relative to others, and social contacts. A global statistic for the 7 indexes was also calculated.

## Main results

At baseline, higher levels of energy, mental health, and social functioning ( $P \leq 0.02$ ) were reported by patients aged  $\geq 55$  y, and higher levels of general health, energy, general functioning, and satisfaction with physical abilities ( $P \leq 0.01$ ) were reported by nonobese patients. Physically active patients reported higher levels than less active patients for most QOL indexes ( $P \leq 0.01$ ). Improvements from baseline were seen for all patient

which suggests that the trial itself may have had a beneficial effect. Nevertheless, patients who did the "right" things, such as increasing physical activity, losing weight, or not smoking, or who had positive social predictors of higher education and higher income had selectively greater QOL improvements. Patients who received drug therapy had greater QOL improvements early on, and these improvements persisted over time.

The authors calibrated QOL index changes in the study by comparing the QOL changes in patients who did or did not have a CVD event, such as stroke. Long-term QOL improvement in the groups with the largest QOL differences was about half as great as the QOL difference between CVD and non-CVD event groups.

groups in most QOL indexes except for general functioning, which decreased. Greater improvement occurred in the active treatment groups compared with placebo for mental health ( $P = 0.01$ ), social functioning ( $P = 0.004$ ), and the global statistic ( $P = 0.007$ ). Acebutolol and chlorthalidone were associated with greater improvement than placebo in most QOL indexes. Differences among the 5 drug groups showed that acebutolol was associated with greater improvement for 3 indexes than the other drugs ( $P < 0.05$ ).

## Conclusions

Quality-of-life measures improved during a 4-year period in patients who received nonpharmacologic intervention and were enrolled in a hypertension treatment study. Additional improvement was associated with antihypertensive drug therapy, particularly  $\beta$ -blockers or diuretics.

*Sources of funding: National Institutes of Health; Pfizer Inc.; Merck, Sharp, and Dohme Research Laboratories.*

*For article reprint: Dr. R.H. Grimm Jr, Shapiro Center, 825 South Eighth Street, Suite 824, Minneapolis, MN 55404, USA. FAX 612-347-7761.*

\*Grimm RH Jr, Flack JM, Grandits GA, et al. JAMA. 1996;275:1549-46.

Abstract and Commentary also published in *ACP Journal Club*. 1997;127:37.

The study included healthy patients. The baseline QOL scores were fairly high, and no patient was  $> 69$  years of age. Despite these limitations, these QOL data firmly support the use of pharmacologic treatment for patients who have mild hypertension, particularly with diuretics and  $\beta$ -blockers.

*Alan Silver, MD, MPH  
Albert Einstein College of Medicine  
New York, New York, USA*

## References

1. Black HR. Treatment of mild hypertension, the more things change. JAMA. 1993;270:767-9.
2. Guyatt GH, Naylor D, Juniper E, et al. Users' guides to the medical literature XII. How to use articles about health-related quality of life. JAMA. 1997;277:1232-7.