Thirty-Six–Item Short-Form Outcomes Following a Randomized Controlled Trial in Type 2 Diabetes

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The goals of clinical interventions in diabetes are to improve not only medical outcomes but health status and health-related quality of life (HRQOL) as well. The Medical Outcomes Study 36-item short form (SF-36) (1) remains the most widely used measure of HRQOL in medical research. We report on change in HRQOL, as assessed using the SF-36, following a randomized controlled trial (RCT) in urban African Americans with type 2 diabetes, a population overrepresented in diabetes prevalence and adverse diabetes outcomes but with relatively little HRQOL research.

RESEARCH DESIGN AND METHODS — Between 1995 and 2000, we conducted a four-arm RCT (2) of the effects of nurse case manager (NCM) and community health worker (CHW) interventions on risk factors for diabetes-related complications in a sample of 186 African Americans with type 2 diabetes in east Baltimore, Maryland. The 2-year trial compared usual care with NCM, CHW, and combined NCM and CHW interventions. The interventions targeted traditional aspects of diabetes care along with socioeconomic factors and home environment. SF-36 was administered at baseline (3) and 2-year follow-up.

RESULTS — One hundred forty-nine persons (84%) completed the 2-year follow-up visit. Pearsons χ^2 analyses and two-sample *t* tests revealed no differences between participants who completed the follow-up and those who did not in demographic characteristics (age, sex, and marital status), socioeconomic status (income and employment), primary clinical outcome of HbA_{1c}, or baseline SF-36 scores.

Data on changes in SF-36 scores from baseline to follow-up were analyzed for the 149 participants. At follow-up, mean SF-36 change scores for usual care revealed lower vitality (−14 points, $P < 0.0001$) and mental health (−8 points, $P = 0.03$), with lower but not statistically significant scores in physical functioning, physical role functioning, and bodily pain.

The combined intervention groups demonstrated modest improvements in HbA_{1c}, triglycerides, and diastolic blood pressure compared with usual care (2). However, these clinical improvements were generally not accompanied by improvements in HRQOL. Similar to usual care, at follow-up, intervention groups demonstrated a pattern of lower scores for mental health (NCM, CHW, and NCM/CHW interventions, all $P < 0.05$), vitality (NCM/CHW intervention, $P < 0.05$), and physical functioning (NCM and NCM/CHW interventions, both $P < 0.05$), with stable scores from baseline to follow-up on other SF-36 scales across intervention groups.

To compare SF-36 change scores for usual care and each intervention group, we conducted linear regression modeling of the relationship between change in SF-36 and intervention group, adjusted for baseline SF-36 scores. Vitality improved for the NCM ($\beta = 8.53$, $P < 0.05$) and CHW ($\beta = 6.34$, $P < 0.05$) interventions compared with usual care. Intervention did not impact physical functioning, physical role functioning, emotional role functioning, social functioning, bodily pain, mental health, or general health in any intervention group.

CONCLUSIONS — Our findings of lack of improvement in HRQOL despite improvements in primary clinical outcomes are consistent with RCTs (4,5) in diabetes with nonminorities that found that SF-36 scores deteriorated or remained stable following interventions demonstrating improved clinical outcomes. These findings raise important issues regarding conceptualization of HRQOL and resulting implications for use, analysis, and interpretation of the SF-36 in diabetes RCTs.

One conceptualization of HRQOL in diabetes is disease burden, including patient distress due to diabetes symptoms, complications, or treatment. Weak associations between SF-36 and diabetes markers, in cross-sectional studies, have been discussed in light of this conceptualization, and use of diabetes-specific HRQOL scales assessing troublesome diabetes-specific symptoms and experiences (6) have been recommended for better sensitivity to burden than the SF-36.

A second conceptualization of HRQOL, impact of disease on physical health, social health, and participation in life activities (7,8), is consistent with SF-36 measurement. This functional health conceptualization of HRQOL re-

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Abbreviations: CHW, community health worker; HRQOL, health-related quality of life; NCM, nurse case manager; RCT, randomized controlled trial; SF-36, 36-item short form.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

quires the consideration of different factors when interpreting HRQOL findings from a diabetes RCT. First, functional health appears to exhibit a pattern of deterioration over time independent of intervention. Our usual care group exhibited lower scores on most SF-36 scales at trial conclusion. Stability in SF-36 scores, therefore, may indicate a positive effect of intervention on HRQOL. Second, variables that moderate functional status (and therefore decline in SF-36 over time) must be accounted for in data analysis and interpretation of findings. Despite gains in clinical markers, impact of older age, for example, on such scales as physical functioning and vitality may be differentially reduced compared with scales for which age is not a moderator. The older age of our sample (mean age 59 years, range 35–75 years) may account in part for the deterioration seen in SF-36 scores. Sample size per arm within this trial did not allow sufficient power to examine HRQOL by age-subgroups to test differential impact on SF-36. However, in trials with larger sample sizes, analysis of age-stratified change in SF-36 is indicated. Third, because HbA_{1c} remains a primary diabetes clinical outcome measure, a functional health conceptualization of HRQOL directs research in the direction of determining A1c thresholds at which functional health status is impacted or at which the SF-36 detects vulnerability to functional health decline (rather than symptom distress). If thresholds are too high to be useful in evaluating the impact of diabetes interventions on HRQOL, then measurement of diabetes-specific HRQOL alone or in addition to SF-36 scores is necessary in RCTs (9).

Increasingly, RCTs in diabetes, like other chronic diseases, are utilizing the Medical Outcomes Study health surveys to assess HRQOL outcomes. Further investigation of issues raised by the present study may facilitate the development of more targeted hypotheses regarding the effect of interventions on HRQOL and careful analysis and interpretation of HRQOL results. When using the Medical Outcomes Study health surveys in particular, without clarification of clinical thresholds for functional health change and moderators of functional health outcomes, there is potential for differential positive impact that interventions may have on HRQOL to be obscured.

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