Depression and Glycemic Control in Elderly Ethnically Diverse Patients With Diabetes

The IDEATel Project

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OBJECTIVE — The purpose of the study was to investigate the effect of comorbid depression on glycemic control and on response to a telemedicine case management intervention for elderly, ethnically diverse diabetic patients.

RESEARCH DESIGN AND METHODS — Medicare beneficiaries in underserved areas were participants (n=1,665) in the Informatics for Diabetes Education and Telemedicine (IDEATel) project and randomized to a telemedicine case management intervention or usual care. The data analyzed include baseline demographics (age, sex, race/ethnicity, marital status, insulin use, years of education, years of diabetes, and pack-years smoked) and measures of glycemic control (HbA_{1c} [A1C]), comorbidity, diabetes symptom severity, functional disability and depression, and 1-year (n=1,578) A1C. The association between depression and glycemic control was analyzed cross-sectionally and prospectively.

RESULTS — At baseline, there was a significant correlation between depression and A1C and a trend for depression to predict A1C when other factors were controlled. However, in prospective analyses, depression did not predict change in A1C, either in the control or intervention group.

CONCLUSIONS — In this large sample of elderly diabetic patients, a weak relationship between depression and A1C was found, but depression did not prospectively predict change in glycemic control. Thus, there is no evidence that depression should be used to exclude patients from interventions. Also, we should evaluate the impact of depression on outcomes other than glycemic control.

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ittle is known about the impact of depression on elderly diabetic patients, a focus of this study. People with diabetes are twice as likely to be depressed as people without chronic disease

(1). Depression is a risk factor for onset of type 2 diabetes (2,3) and is associated with hyperglycemia, complications, smoking, mortality, and poorer adherence (4-8). There are conflicting findings

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Abbreviations: CARE, Comprehensive Assessment and Referral Evaluation; CMMS, Center for Medicare and Medicaid Services; IDEATel, Informatics for Diabetes Education and Telemedicine; PCP, primary care provider.

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

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concerning depression and glycemic control (9-12) and whether treatment of depression results in improved glycemic control (13-15).

Although diabetes is a disease of advancing age, little is known about comorbid depression for elderly diabetic patients. Diabetes prevalence in the Medicare population increased 36%, and adjusted diabetes incidence increased 36.9% from 1993 to 2001 (16). It has been estimated that 20-25% of the elderly meet criteria for impaired glucose tolerance, and 20-30% have undiagnosed diabetes (17-19). The number of adults aged >65 years will double over the next 20-30 years, and the incidence of diabetes will dramatically increase (20,21). Given increases in life expectancy, many diabetic patients will experience complications and impaired physical and emotional quality of life (22,23). Prevalence estimates of comorbid depression and diabetes in the elderly range from 4.5% (24) to 16% (25), depending on samples, measures, and criteria. Finkelstein et al. (26) found that the diagnosed annual prevalence rate of major depression in the elderly increases with age, and comorbidity is associated with significantly greater health care utilization. Thus, the impact of depression on elderly diabetic patients is important to understand.

Analysis of data from the ELDER (Evaluating Long-Term Diabetes Self-Management Among Elder Rural Adults) Study found that depression related to sex, education, living arrangement, BMI, number of prescription medications, number of chronic conditions, and physical functioning (25). In another study, depression was actively addressed by a depression care manager, and elderly participants reported improvements in depressive symptoms, exercise adherence, and overall functioning but not in glycemic control (27). One purpose of this study was to assess the potential impact of depression on glycemic control for elderly diabetic patients.

It is a common clinical assumption that depression interferes with one's abil-

ity to benefit from diabetes interventions, and depressed individuals are frequently excluded from intervention efficacy trials. However, to our knowledge, this assumption has never been tested. A second purpose of the study was to assess the impact of depression on the glycemic control outcomes of a case management intervention. We hypothesized that depression would result in poorer outcomes. In addition, as depression can promote unhealthy lifestyle behaviors (e.g., weight gain, smoking), we hypothesized that depression would also predict poorer outcomes for usual care participants.

RESEARCH DESIGN AND

METHODS— Subjects were participants in the Informatics for Diabetes Education and Telemedicine (IDEATel) project (28,29), a demonstration project funded by the Center for Medicare and Medicaid Services (CMMS). Medicare beneficiaries with diabetes living in medically underserved areas were enrolled to evaluate the feasibility, effectiveness, and cost-effectiveness of telemedicine with this population. Subjects were recruited through primary care providers (PCPs) in urban and rural medically underserved areas and were included if they were ≥55 years of age, receiving Medicare, and had diabetes (defined by physician's diagnosis and being treated with diet, oral hypoglycemic agents, or insulin). Excluded were those who had moderate/severe cognitive, visual, or physical impairments or severe comorbid disease. Subjects were randomized to a telemedicine case management intervention or usual care. Intervention subjects received a home telemedicine unit, i.e., a web-enabled computer used to upload blood pressure and blood glucose measurements, to videoconference with a nurse case manager and dietitian, and to access individualized graphic data displays and educational materials. The nurse case managers provided diabetes education and, under the supervision of an endocrinologist, treatment planning and consultation to PCPs who maintained treatment decision authority for their patients. A separate team of trained research nurses conducted physical and psychosocial assessments at baseline and 1-year follow-up. Over the 1st year of involvement, the mean number of home televisits (~30 min, every 2-6 weeks depending on glycemic control) was 28.3 ± 15.2 (median 28), with a mean number of blood glucose uploads (560.2) and blood pressure uploads

(184.6) indicating intensive program involvement. The data analyzed for the present study includes baseline (n = 1,665) subject demographics (age, sex, race/ethnicity, marital status, insulin use, education, years of diabetes, and pack-years smoked) and measures of glycemic control, comorbidity, diabetes symptom severity, functional disability and depression, and 1-year (n = 1,578) measure of glycemic control. Although depression was measured at baseline, it was not used as an exclusion criterion.

Measures

SHORT-Comprehensive Assessment and Referral Evaluation Depression Scale (30,31). The SHORT-Comprehensive Assessment and Referral Evaluation (CARE) Depression Scale is a brief version of the CARE and measures depression in the elderly and is chosen for IDEATel because it has been used with ethnically diverse populations. Internal consistency reliability estimates were 0.87 for development samples, and interrater reliability was 0.94 (32). Cronbach's α for the current sample was 0.86. The evidence for concurrent validity was high (e.g., correlation of 0.75 with diagnosis) (33). The SHORT-CARE includes diagnostic items that correspond to DSM criteria, and cut scores have been developed for classification of depression (31). A cutoff of seven yields the highest sensitivity and specificity for clinical depression

Charlson Comorbidity Index (35). The Charlson Comorbidity Index is a 17-item self-report of medical conditions. Weights (0–6) are assigned to various conditions reported. The weights are then added with an algorithm to ensure that the same condition is represented only once. It correlates significantly with short-term outcomes (36,37).

Type 2 Diabetes Symptom Checklist. The Type 2 Diabetes Symptom Checklist assesses six dimensions of diabetes-related symptoms: hyperglycemic, hypoglycemic, ophthamologic, psychologic, cardiovascular, and neuropathic (38). Test-retest reliability ranged from 0.79 to 0.94. Internal consistency estimates ranged from 0.76 to 0.95. Cronbach's α for the current sample was 0.91.

The Activities of Daily Living Scale of the CARE. The Activities of Daily Living Scale of the CARE is a measure of functional disabilities used to assess elderly individuals of different races, ethnicities, and community settings (30,39,40). Con-

current and predictive validity is good (32,33). Cronbach α for the development sample were 0.84–0.95, and for the current sample it was 0.93.

Glycemic control was measured using HbA_{1c} (A1C) analyzed by boronate affinity chromatography with the Primus CLC 383 (Primus, Kansas City, MO).

Statistical analyses

IDEATel participants were enrolled through 700 PCPs (325 downstate and 375 upstate) and randomized within the practice. Therefore, all statistical analyses were adjusted for clustering within the PCP practices.

Variables included as covariates were age, sex, race/ethnicity, marital status, years of education, years of diabetes, insulin use, pack-years smoked, comorbidity, functional disability, and diabetes symptom severity. Variables were included based on clinical importance and preliminary analysis. Pearson's correlation and t tests were used to determine significant associations between the possible covariates and baseline measures of depression and glycemic control. Variables were included as covariates if they had a *P* value of \leq 0.10 with the baseline data. Variables included in the baseline models were also included in the 1-year outcome models.

The primary analysis was of the relationship between baseline subject variables and outcome measures, with depression as the main independent variable and change in A1C (1-year A1C controlling for baseline A1C) as the outcome variable. To perform prospective analyses, a mixed-model approach with random effect to adjust for clustering within the PCP practice was implemented, using the SAS PROC MIXED. Variance components covariance structure was used in all analyses. Each analysis controlled for baseline A1C and all subject variables, including functional disability and comorbidity, two factors that are critical to outcomes of the elderly.

RESULTS

IDEATel recruitment and retention

Of 9,597 potential subjects assessed for eligibility, 929 were excluded by CMMS (e.g., not in CMMS system, died), and 6,467 were excluded for other reasons (e.g., refused, too sick, did not have diabetes, PCP refused). Telephone screens were accomplished for 2,201 individuals, 235 were excluded (e.g., vision, cognitive

Depression and glycemic control

Table 1—Descriptive statistics of the subject sample

| | n | Means ± 5 | SI | | |
|-------------------------------------|--------------|----------------|-----|--|--|
| Age | 1,665 | 70.8 ± 6.6 | 6 | | |
| Years of education | 1,663 | $9.8 \pm 4.$ | 1 | | |
| Years since diagnosed with diabetes | 1,646 | 11.1 ± 9. | 4 | | |
| Pack-years smoked | 1,636 | 19.9 ± 32 | 2.5 | | |
| Charlson Comorbidity Index | 1,663 | 2.9 ± 1.9 | 9 | | |
| Type 2 Symptom Severity Score | 1,662 | 31.3 ± 19 |).2 | | |
| Function-ADL | 1,663 | 6.3 ± 6.0 | 6 | | |
| Depression | 1,663 | 5.7 ± 4.8 | 8 | | |
| A1C | 1,631 | 7.4 ± 1.5 | 5 | | |
| | | n (%) | | | |
| Sex | | | | | |
| Male | 6 | 519 (37.2) | | | |
| Female | 1,046 (62.8) | | | | |
| Single/never married | | | | | |
| No | 1,470 (88.4) | | | | |
| Yes | 193 (11.6) | | | | |
| Participant takes insulin | | | | | |
| to control diabetes? | | | | | |
| No | 1,173 (70.5) | | | | |
| Yes | 491 (29.5) | | | | |
| Race/ethnicity | | | | | |
| African American | | .48 (14.9) | | | |
| Hispanic | | 86 (35.2) | | | |
| White (non-Hispanic) | 8 | 321 (49.4) | | | |
| Other | | 8 (0.5) | | | |

Function-ADL: SHORT-CARE Activities of Daily Living scale. Depression: SHORT-CARE Depression scale.

impairment), and 301 were not randomized (e.g., changed minds), leaving 1,665 randomized (844 intervention, 821 usual care). For prospective analyses, 105 usual care and 201 intervention subjects dropped out or were lost to follow-up. Subjects who completed the 1-year exam did not differ significantly from those who did not on age, race/ethnicity, sex, or baseline medical data. The baseline demographic and clinical data did not differ for the intervention and control groups (Table 1).

IDEATel 1-year results

Detailed analyses of the results of the IDEATel project have been reported (41). Limited data are provided here in order to provide a context for this study. Mean A1C decreased in the intervention group from 7.35 to 6.97% and in the control group from 7.42 to 7.17%. When comparing these group changes, the net adjusted reduction was 0.18% (P = 0.006). When the data from the subgroup of sub-

jects with baseline A1C >7% were analyzed, these differences were greater, showing a net adjusted reduction of 0.32% (P = 0.002) of intervention versus control subjects.

Baseline correlates of depression

See Table 2. There was a significant correlation between depression and A1C (r=0.104), indicating that depression was associated with poorer glycemic control at baseline. Subjects reporting more depressive symptoms were younger (r=-0.159), female (t=0.210), Caucasian or Hispanic (t=0.284), never married (t=0.050), less educated (r=-0.207), insulin users (t=0.084), heavier smokers (r=0.061), and reported more medical comorbidities (r=0.218) and more diabetes-related symptoms (r=0.284).

Baseline predictors of glycemic control

Table 3 provides data on the relationship between baseline depressive symptoms and A1C. In each analysis, all other covariates were controlled. There was a trend for depression to predict baseline A1C (estimate = 0.026). Other predictors of higher A1C were being Caucasian (estimate = 0.803), male (estimate =

-0.172), using insulin (estimate = 0.476), having more years of education (estimate = 0.013), having more years of diabetes (estimate = 0.016), having more diabetes symptoms (estimate = 0.006), and having poorer activity of daily living function (estimate = 0.047).

Prospective analyses of depression as a predictor of glycemic control

Depression was examined using three different measurement approaches (Table 4). In each analysis, we also examined whether the two groups, intervention and control, differed in whether depression predicted A1C (depression × group interaction term), and we ran separate analyses for the two groups to further assess this issue.

The first analysis was of depressive symptoms, treated as a continuous variable, predicting change in A1C (controlling for baseline A1C and other subject variables). Baseline depressive symptoms did not predict change in A1C (estimate = 0.016, P > 0.350), neither for the control (estimate = 0.001, P > 0.911) nor intervention (estimate = -0.003, P > 0.769) group.

Next, depression was treated as a dichotomous variable, and the cutoff score

Table 2—Baseline correlates and mean group differences of baseline depressive symptoms (SHORT-CARE)

| | SHORT-CARE | P value |
|--------------------------------|-----------------|----------|
| Age | r = -0.159 | < 0.001 |
| Years of education | r = -0.207 | < 0.001 |
| Years of diabetes | r = 0.010 | 0.70 |
| Smoking pack-years | r = -0.037 | 0.13 |
| Comorbidity | r = 0.218 | < 0.001 |
| Diabetes symptom severity | r = 0.555 | < 0.001 |
| Function-ADL | r = 0.480 | < 0.001 |
| Glycemic control (A1C) | r = 0.104 | < 0.001 |
| | Mean ± SD | P value* |
| Sex | | |
| Male | 4.37 ± 4.16 | < 0.001 |
| Female | 6.44 ± 4.95 | |
| Race/ethnicity | | |
| Black/Hispanic/other | 6.85 ± 5.39 | < 0.001 |
| White | 4.47 ± 3.69 | |
| Marital status | | |
| Other (married, widowed, etc.) | 5.58 ± 4.73 | 0.04 |
| Single/never married | 6.33 ± 5.06 | |
| Insulin use | | |
| No | 5.41 ± 4.70 | 0.001 |
| Yes | 6.29 ± 4.90 | |
| D. 1 | | 1 1 1 1 |

Diabetes symptom severity: higher score = more severe symptoms. Glycemic control: higher percent = poorer glycemic control. r = Pearson correlation coefficient. *t test. Function-ADL: SHORT-CARE Activities of Daily Living scale.

Table 3—Mixed-model* analyses of baseline subject covariates and depressive symptoms as predictors of baseline glycemic control (A1C)

A1C†

| | (n = 1,578) | | | | |
|--------------------|-------------|-------|--------------|--|--|
| | Estimate | SE | Significance | | |
| Constant | 7.077 | 0.447 | < 0.0001 | | |
| Race/ethnicity | 0.803 | 0.132 | < 0.0001 | | |
| Age | -0.006 | 0.006 | 0.288 | | |
| Sex | -0.172 | 0.076 | 0.024 | | |
| Marital status | 0.109 | 0.123 | 0.372 | | |
| Education | 0.013 | 0.011 | 0.226 | | |
| Years of diabetes | 0.016 | 0.004 | 0.000 | | |
| Insulin | 0.476 | 0.089 | < 0.0001 | | |
| Smoking pack-years | 0.001 | 0.001 | 0.544 | | |
| Comorbidity | -0.014 | 0.020 | 0.467 | | |
| Symptom severity | 0.006 | 0.003 | 0.012 | | |
| Function-ADL | -0.014 | 0.007 | 0.047 | | |
| Depression | 0.026 | 0.014 | 0.066 | | |
| Depression × race | -0.024 | 0.017 | 0.149 | | |

Sex: 1 = male; 2 = female. Race: 1 = white; 0 = black/Hispanic/other. Marital status: 1 = single/never married; 0 = other (married, widowed, etc.). Insulin use: 1 = yes; 0 = no. Diabetes symptom severity: higher score = more severe symptoms. Comorbidity: Charlson Index, higher score = more comorbid conditions. Function-ADL: SHORT-CARE Activities of Daily Living scale. Depression: SHORT-CARE Depression scale. *Adjusted for clustering within PCP. PCP was treated as a random effect. Variance components covariance structure used. Each analysis controlled for all other covariates. †Adjusted for group heterogeneity in cluster and residual variances.

of seven was used to define depressed versus not-depressed groups, as recommended (34). At baseline, 31.7% (n = 528) exceeded the cutoff, while at fol-

low-up 27.8% (n = 393) did so. Baseline depression did not predict change in A1C (estimate = 0.164, P > 0.105), neither for the control (estimate = 0.166, P >

0.164) nor intervention (estimate = 0.141, P > 0.156) group.

Finally, depression was defined as use of antidepressant medication. A study of the Diabetes Prevention Program research group found that individuals who take antidepressant medications often have a diagnosis of depression but do not have higher depression measure scores, and they argue for using this factor as a marker of depression (42). At baseline, antidepressant use did not correlate with any of the medical variables. In prospective analvses, depression did not predict change in A1C (estimate = -0.101, P > 0.293), neither for the control (estimate = -0.040, P > 0.754) nor intervention (estimate = 0.053, P > 0.641) group.

In all analyses, racial/ethnic groups did not differ on whether depression was a predictor of change in A1C. There were three factors that did predict glycemic control: age (older subjects had lower 1-year A1C), race (Caucasian subjects had higher 1-year A1C), and insulin use (insulin users had higher 1-year A1C).

CONCLUSIONS — In this large sample of elderly diabetic patients, we did not find evidence that depression prospectively predicts change in glycemic control, neither for the group that participated in the IDEATel intervention

Table 4—Predicting follow-up A1C from baseline covariates using three markers of depression, controlling for covariates, and adjusted for PCP clustering*

| | Depression | | | | | | | | |
|------------------------------|----------------------------|-------|-----------------------------|----------|---------------------------------|--------------|----------|--------|--------------|
| | Continuous ($n = 1,320$) | | Dichotomous ($n = 1,320$) | | Antidepressants ($n = 1,312$) | | | | |
| | Estimate | SE | Significance | Estimate | SE | Significance | Estimate | SE | Significance |
| Constant | 4.372 | 0.387 | < 0.0001 | 4.328 | 0.3859 | < 0.0001 | 4.3751 | 0.386 | < 0.0001 |
| Baseline A1C | 0.430 | 0.020 | < 0.0001 | 0.429 | 0.020 | < 0.0001 | 0.4283 | 0.020 | < 0.0001 |
| Group (experimental/control) | 0.156 | 0.088 | 0.076 | 0.150 | 0.068 | 0.028 | 0.179 | 0.0625 | 0.004 |
| Race/ethnicity | 0.201 | 0.079 | 0.011 | 0.180 | 0.078 | 0.022 | 0.196 | 0.079 | 0.013 |
| Age | -0.008 | 0.005 | 0.085 | -0.007 | 0.005 | 0.114 | -0.008 | 0.005 | 0.076 |
| Sex | -0.027 | 0.062 | 0.667 | -0.035 | 0.061 | 0.575 | -0.022 | 0.062 | 0.727 |
| Marital status | -0.065 | 0.088 | 0.461 | -0.061 | 0.088 | 0.493 | -0.068 | 0.089 | 0.444 |
| Years of education | 0.000 | 0.008 | 0.994 | 0.001 | 0.008 | 0.938 | 0.000 | 0.008 | 0.980 |
| Years of diabetes | 0.004 | 0.004 | 0.226 | 0.005 | 0.004 | 0.193 | 0.005 | 0.004 | 0.188 |
| Insulin use | 0.222 | 0.072 | 0.002 | 0.219 | 0.072 | 0.002 | 0.224 | 0.072 | 0.002 |
| Smoking pack-years | -0.001 | 0.001 | 0.46 | -0.001 | 0.001 | 0.517 | -0.001 | 0.001 | 0.462 |
| Comorbidity | 0.000 | 0.017 | 0.997 | -0.001 | 0.017 | 0.972 | 0.001 | 0.017 | 0.975 |
| Diabetes symptom severity | 0.003 | 0.002 | 0.131 | 0.002 | 0.002 | 0.371 | 0.003 | 0.002 | 0.126 |
| Function-ADL | -0.006 | 0.005 | 0.251 | -0.009 | 0.005 | 0.095 | -0.007 | 0.005 | 0.203 |
| Depression | -0.002 | 0.009 | 0.809 | 0.142 | 0.093 | 0.124 | 0.054 | 0.112 | 0.627 |
| Depression × group | 0.000 | 0.012 | 0.975 | -0.006 | 0.123 | 0.964 | -0.148 | 0.162 | 0.360 |

Marital status: 1 = subject single/never married; 0 = other (married, widowed, etc.). Years of diabetes: number of years since you were diagnosed with diabetes. Function-ADL: SHORT-CARE Activities of Daily Living scale. Depression: SHORT-CARE Depression scale. Antidepressants: participant takes antidepressant medications (0 = no; 1 = yes). *Adjusted for clustering within PCP and group heterogeneity in cluster and residual variances. Variance components covariance structure used.

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nor for those who received usual care. Whether we defined depression as a continuous variable (i.e., number and severity of depressive symptoms), as a dichotomous variable (i.e., depressed/not depressed), or as use of antidepressants, baseline depression did not predict change in A1C. We note that IDEATel did not target depression as a primary outcome, nor were patients systematically excluded due to depression scores, although PCPs may have screened out their more depressed patients before telephone screen.

We hypothesized that depressed patients would derive less benefit from the intervention, as the hopelessness/helplessness of depression might interfere with taking an active health care role. We did not find this to be the case. We also hypothesized that depressed patients receiving usual care would demonstrate poorer glycemic control 1 year later; this hypothesis was not supported.

Participants reported more depressive symptoms if they were female, never married, less educated, heavier smokers, had more comorbid medical conditions, and poorer glycemic control, findings similar to other reports (9,12). This supports the findings of relationships between depression and varied negative outcomes, confirms the limited research on the impact of depression on the elderly, and extends the data to an ethnically diverse sample of elders, a group that is often underrepresented in research.

Studies that have explored the relationship between depression and glycemic control have yielded inconclusive findings. While we did find a significant baseline relationship, this became a trend when other variables were controlled; thus, the relationship was not strong. If a stronger relationship exists, it may have been masked by limited variability in glycemic control or depression. However, in light of a recent population-based study that found no relationship between depression and hyperglycemia when comorbid diseases were controlled (12), one might reasonably conclude that the relationship between depression and glycemic control is a weak one for this sample of elderly individuals. We do not know if results would have been different for other age-groups.

There are several limitations of the study. As noted earlier, the limited variability in A1C or depression might have masked a relationship between the two. We used a self-report measure of depression that may not have been sufficiently

sensitive. Also, we do not have information about the individuals who were excluded before the telephone screen, other than knowing that they were significantly older (though still elderly) than the final sample (73.9 vs. 70.8 years mean age). Finally, $\sim 36\%$ of the drop-outs (n =306), as compared with 31.7% of the participants, scored above the cutoff for clinical depression. The possibility that PCPs may have excluded their most depressed patients and that a greater percentage of subjects lost to follow-up were depressed may have affected our ability to find a relationship between depression and follow-up A1C.

Without evidence to the contrary, depression should not be used to exclude elderly patients from participation in interventions that target medical outcomes. Future research should assess the impact of depression on outcomes other than glycemic control. Finally, further research should specifically focus on the elderly with comorbid depression and diabetes, given the paucity of research with this ever-growing group.

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