HEALTH CARE REFORM

Comparative Effectiveness of Goal Setting in Diabetes Mellitus Group Clinics

Randomized Clinical Trial

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Background: Diabetes mellitus (DM) group clinics can effectively control hypertension, but data to support glycemic control are equivocal. This study evaluated the comparative effectiveness of 2 DM group clinic interventions on glycosylated hemoglobin (HbA1c) levels in primary care.

Methods: Eighty-seven participants were recruited from a DM registry of a single regional Veterans Affairs medical center to participate in an open, randomized comparative effectiveness study. Two primary care–based DM group interventions of 3 months’ duration were compared. Empowering Patients in Care (EPIC) was a clinician-led, patient-centered group clinic consisting of 4 sessions on setting self-management action plans (diet, exercise, home monitoring, medications, etc) and communicating about progress with action plans. The comparison intervention consisted of group education sessions with a DM educator and dietician followed by an additional visit with one’s primary care provider. Hemoglobin A1c levels were compared after intervention and at the 1-year follow-up.

Results: Participants in the EPIC intervention had significantly greater improvements in HbA1c levels immediately following the active intervention (8.86%-8.04% vs 8.74%-8.70% of total hemoglobin; mean [SD] between-group difference 0.67% [1.3%]; P = .03), and these differences persisted at the 1 year follow-up (0.59% [1.4%], P = .05). A repeated-measures analysis using all study time points found a significant time-by-treatment interaction effect on HbA1c levels favoring the EPIC intervention (F2,85=3.55; P = .03). The effect of the time-by-treatment interaction seems to be partially mediated by DM self-efficacy (F1,85=10.39; P = .002).

Conclusion: Primary care–based DM group clinics that include structured goal-setting approaches to self-management can significantly improve HbA1c levels after intervention and maintain improvements for 1 year.

Trial Registration: clinicaltrials.gov Identifier: NCT00481286

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DIABETES MELLITUS (DM) is a serious and growing public health problem.1 The prevalence and morbidity of DM are greater among older adults who often have multiple chronic morbidities.2,3 Self-management skills are an essential means of reducing morbidity and health services use among older, comorbid patients with DM.4,5 However, delivery of effective self-management education and support can be difficult in traditional primary care, even among patients who have access to care, medications, and DM educators but who also have persistently uncontrolled DM.6 Many primary care clinics have few personnel trained to effectively deliver self-management education and support for chronic DM care. Furthermore, DM self-management is often poorly integrated with the physician-patient encounter, and evidence-linking self-management activities and health outcomes are often indirect at best.5,7 Rather than a parallel form of treatment, self-management functions best as a method whereby patients integrate specific DM treatment recommendations (medications, home monitoring, diet and exercise, prescriptions, etc) into the context of their daily routines.7 Effective self-management includes collaborative framing of specific self-management goals (goal setting), feedback regarding structured activities patients do on a daily basis to reach their self-management goals (action plans), and proactive communication with clinicians about the success of self-management and the treatment plan as a whole.8,9 The effectiveness of an action plan can be enhanced by increasing patients’ confi-

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The effectiveness of both groups was compared using DM clinic approaches in a chronic care population with a comparative effectiveness trial of alternative DM group education plus routine primary care with a DM clinic intervention.9

Shared medical appointments (group clinics) are a potential method of integrating self-management support with routine DM care to reach the patients with treated but uncontrolled DM. Group clinics are associated with improvements in some DM outcomes and urgent care visits.11-13 However, randomized studies of group clinics using intensive medical management coupled with didactic models of self-management education have demonstrated mixed results when compared with routine DM care.13,14 These DM group clinics have been critiqued for focusing largely on the efficacy of medical management and a clinician-centric approach to DM education.17 To adequately determine the effectiveness of DM group clinics relative to routine DM care, medical management should be coupled with interventions that focus on how treatment plans are translated by patients into self-management goals (goal setting) and then integrated into the context of their daily lives (action plans).

Our objective was to conduct a randomized comparative effectiveness trial of alternative DM group clinic approaches in a chronic care population with treated but uncontrolled DM. The trial compared DM group education plus routine primary care with a DM group intervention focused on training patients to integrate their health care providers' treatment plans into collaborative self-management goals and action plans. The effectiveness of both groups was compared using hemoglobin A1c (HbA1c) levels and DM self-efficacy immediately after the interventions and at 1-year follow-up.

**STUDY DESIGN AND PARTICIPANTS**

This study was an open, randomized pilot trial comparing the effectiveness of 2 group self-management interventions on glycemic control. The study enrolled patients receiving routine primary care at the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) in Houston, Texas. We screened and recruited participants from August 2007 through March 2008. The trial compared a novel intervention called “Empowering Patients in Chronic Care” (EPIC), with a DM and nutrition education intervention. After the active intervention period, participants in both arms received usual primary care. The primary outcome measure was improvement in glycosylated HbA1c levels at the conclusion of the active intervention period and at 1 year after randomization.

Study participants were recruited overwhelmingly from the MEDVAMC primary care patient registry. Referrals from primary care providers (PCPs) and advertisements in outpatient clinics were infrequent sources of study participants. Patients in the primary care registry were sent an invitation letter describing the study and participant expectations, including attendance at multiple group visits if they met the following eligibility criteria. Inclusion criteria defined eligibility to individuals 50 to 90 years old who had a PCP and a previous diagnosis of type 2 DM with a mean HbA1c level of at least 7.5% of total hemoglobin on all measurements in the 6 months prior to study entry. (To convert HbA1c to proportion of total hemoglobin, multiply by 0.01.) Patients excluded if they had a diagnosis of dementia or a serum creatinine level of at least 2.5 mg/dL. (To convert creatinine to micromoles per liter, multiply by 88.4.) Participants responding to the invitation letter or advertisement were asked to contact study personnel, who then obtained informed consent and baseline assessments prior to randomization. Participants with an HbA1c level lower than 7.0% of total hemoglobin at baseline despite higher historic HbA1c levels were excluded.

The study was approved by the Baylor College of Medicine, Houston, Texas, institutional review board and by the MEDVAMC research and development committee.

**RANDOMIZATION AND GROUP ASSIGNMENT**

After enrollment, participants were randomized to either the EPIC or traditional education interventions using a block randomization of 10. Allocation of treatment group assignment was blinded using sequentially numbered and sealed envelopes. Research personnel assisted with the assignment of participants to cohesive groups of 5 to 7 individuals for both the EPIC and traditional education interventions. Group assignments were maintained for all intervention sessions to facilitate peer interactions and relationships within groups.

**INTERVENTIONS**

The EPIC Intervention consisted of 4 group sessions occurring every 3 weeks over a 3-month period (Figure 1). Each session consisted of 1 hour of group interaction facilitated by a study clinician trained in goal setting and action planning methods.6,10 After the hour-long group session, each participant had 10 minutes of individual interaction with the study clinician. Peer discussion of the intervention contents was encouraged while waiting for one’s interaction with the clinician. Each session had a different overall theme focusing on “The Diabetes ABCs” (HbA1c level, blood pressure, cholesterol level), “How...
to Make Diabetes Goals and Action Plans,” “How to Talk to Your Doctor,” and “Action Plan Feedback” (eAppendix; http://www.archinternmed.com). The Diabetes ABCs session instructed participants about common risk markers for DM (i.e., HbA1c level, systolic blood pressure, and cholesterol level) and provided participants with their individual values for these 3 markers, taken from baseline measurements. The second session introduced elementary principles of goal-setting theory (goal specificity, difficulty, and importance) and guided participants in designing personalized DM goals and action plans. Goals focused primarily on diet and exercise changes, home monitoring of blood glucose and medication effects, and communication with PCPs about medications. Participants also developed goals about sleep, pain, and other barriers to self-management. The third session described and modeled proactive patient behavior, effective physician-patient communication, and how to develop and obtain feedback on goals and action plans during clinical encounters.9,20 The fourth session allowed for constructive reporting and feedback on participants’ performance with their action plans with peers and the study clinician. Three study clinicians, primary care physicians at the MEDVAMC, directed the sessions (see eAppendix for descriptions of each session and information about training of study clinicians).

For each EPIC session, the group interaction was divided into three 20-minute blocks, each conveying the session theme using different modalities: (1) clinician-led discussion of didactic materials from a participant manual, (2) group discussion of problem-based exercises from the manual, and (3) peer-supported application of the session theme to one’s daily life (Figure 1). During the one-on-one consultation with the study clinician, participants discussed their DM status, received feedback on their specific DM goal and action plan, and addressed medication-related issues. Study clinicians sent a research note to PCPs after each session consisting of participants’ Diabetes ABCs status, the specific DM goals and action plans discussed, and any changes made to prescribed medication type and dosage due to adverse effects or other issues raised by patients. Action plans for nearly all patients included taking medications prescribed by PCPs and discussing subjective and objective effects of medications with PCPs.

Participants randomized to the traditional education intervention attended 2 distinct group sessions led by a DM nurse educator and a certified DM dietician. The nurse educator covered DM topics, including DM physiologic characteristics, health problems, types of DM, and medications and dosing. At the end of the didactic portion, each participant received a 10-minute individual consultation with the nurse educator regarding their current HbA1c levels. The dietician covered topics about knowledge of DM, reading food labels, preparing meals, and portion size and control. Each session was 2 hours long. In addition, participants had a 20- to 30-minute consultation scheduled after completing the education groups with their PCP. The PCPs were instructed to focus on DM self-management and treatment plans.

OUTCOMES AND MEASUREMENTS

The primary outcome was HbA1c level measured by the clinical laboratory at the MEDVAMC using a standardized method of ion-exchange liquid chromatography. Participants completed questionnaires at baseline that included sociodemographic information, a DM self-efficacy scale,21 and a DM-specific knowledge and understanding scale.22 The Diabetes Self-efficacy Scale is an 8-item measure evaluating respondents’ confidence in performing specific DM management tasks, such as diet, exercise, blood glucose management, and lifestyle domains. Each item uses a 10-point response scale with higher scores corresponding to greater self-efficacy.21 Individual Diabetes Self-efficacy scores represent the mean value of all 8 items; therefore, mean Diabetes Self-efficacy scores range from 1 to 10. A trained research assistant extracted clinical information (e.g., comorbidities, height, weight, and blood pressure) from patients’ medical records at the time of enrollment. The HbA1c levels and a patient survey containing the Diabetes Self-efficacy measure were collected at baseline, at the conclusion of the active interventions (3 months), and 1 year after enrollment. Study participants did not differ significantly in terms of age, race, and comorbidity from the typical MEDVAMC primary care patient with DM (see Table 1 for P values).

POWER AND STATISTICAL ANALYSES

Our original power calculation called for 49 individuals in each group to identify a moderate effect size for between-group reductions of HbA1c values (mean [SD], 0.6% [1.05%]) after intervention assuming 80% power and 5% 2-sided α. We anticipated minimal losses given the very low rate of attrition among primary care users of the VA system and regularity of HbA1c measurements. Our final study sample consisted of 87 individuals due to exclusions at baseline (Figure 2) and the pilot design of the study limiting additional recruitment. Statistical analyses were 2-tailed with an α value of 0.05, performed using SAS software (version 9.1; SAS Institute Inc, Cary, North Carolina). We made comparisons between the EPIC and traditional education intervention groups at baseline using unpaired t tests for continuous variables and χ² tests for categorical variables. Unpaired t tests were also used to compare differ-
This interaction would indicate that there was a difference between the EPIC and traditional education interventions at baseline, and the time effect measured differences between the EPIC and traditional education interventions. A significant value for the time-by-treatment interaction variable are of most interest for this secondary mediation analysis.

### RESULTS

#### PARTICIPANTS AND BASELINE CHARACTERISTICS

Figure 2 shows the flow of participants through the study. Of 502 patients who were screened for eligibility criteria and expressed interest, 102 potential participants attended an enrollment session. Among those attending the enrollment session, 4 individuals declined participation, 2 refused to be randomized, and 2 never received a baseline HbA1c measurement. An additional 7 participants who consented were excluded because their HbA1c levels at baseline were lower than 7.0% of total hemoglobin. The final study sample of 87 participants completed informed consent and underwent randomization. Forty-three of the 45 participants (96%) randomized to EPIC attended some or all of the intervention sessions, and all 42 participants randomized to the traditional education group attended some or all of the intervention sessions. Only 1 person from each intervention group was lost to follow-up. These individuals had no postintervention or 1-year HbA1c measurements and could not be included in the final analytic sample. Diabetes Self-efficacy Scale data were available for 75 participants (86%) at the 3-month follow-up and 76 participants (87%) at the 1-year follow-up.

Participants in the EPIC and traditional education interventions were similar at baseline across a range of sociodemographic and clinical variables, including HbA1c level, systolic blood pressure, body mass index, and duration of DM (Table 1). All participants were chronically treated patients with DM with good access to primary care and DM education. Consistent with an older US veteran population, the sample was overwhelmingly male, had multiple morbidities, and was of heterogeneous race. No differences were noted at baseline between the intervention groups in the Diabetes Self-efficacy scale, Knowledge and Understanding of Diabetes Self-management scale, and Perceived General Health Status scale.

#### OUTCOME MEASURES

Significant differences between the 2 interventions were observed in HbA1c levels immediately following the active interventions (Table 2), and the between-group differences remained clinically and statistically significant at 1-year follow-up (Table 2). Diabetes mellitus self-efficacy measures improved immediately after the intervention (3-month data collection) compared with baseline in both intervention groups (Table 2). The self-efficacy measures at 3 months were significantly higher...
in the EPIC intervention group compared with those in the education intervention group (mean [SD] group difference, 0.84 [1.56]; \( P = .02 \)). Diabetes Self-efficacy scores returned to baseline levels at the 1-year data collection, with modest (nonsignificant) between-group differences (0.62 [1.94]; \( P = .17 \)).

Longitudinal differences in HbA\(_1c\) levels across study time periods are illustrated in Figure 3 with a marked divergence between intervention groups at the 3-month data collection, which held constant at the 1-year data collection. These observed longitudinal differences (Figure 3) are both clinically and statistically significant when considering the results of the repeated-measures analysis for HbA\(_1c\) levels. There was a statistically significant time-by-intervention group interaction \( (F_{2,85} = 4.69; P = .01) \) and a significant effect for time regardless of group \( (F_{2,85} = 4.69; P = .01) \). The effect of treatment group alone was not significant \( (F_{1,85} = 2.83; P = .10) \).

A secondary repeated-measures analysis was also performed to evaluate the mediation effect of DM self-efficacy on the primary outcome relationship of the time-by-treatment interaction and longitudinal differences in HbA\(_1c\) levels. This analysis demonstrated significant effects for DM self-efficacy \( (F_{1,85} = 10.39; P = .002) \). After adjusting for self-efficacy, the time-by-treatment interaction on longitudinal HbA\(_1c\) values became nonsignificant \( (F_{2,85} = 2.93; P = .06) \).

The results of this randomized comparative effectiveness study demonstrated that clinically significant improvements in HbA\(_1c\) can be achieved after a 3-month, 4-session group clinic intervention using the EPIC approach to self-management and medical care. The objective of EPIC was to promote collaborative development of goals and action plans by participants and study clinicians. Action plans assist patients in integrating specific aspects of the DM treatment plan into everyday routines, increasing the likelihood of implementing lifestyle changes, adherence to medications, and performing home monitoring. Enhanced use of self-management likely produced HbA\(_1c\) improvements after intervention that were maintained over the year, given the corresponding changes in self-efficacy. EPIC participants were also trained to communicate their progress with an action plan and receive feedback from PCPs. These aspects of the intervention were less successful given the plateau in HbA\(_1c\) improvements after intervention. In contrast, the traditional education intervention participants had only modest and clinically insignificant improvements in HbA\(_1c\) levels at both 3 months and 1 year. The group education sessions and the individual PCP follow-up rely on a traditional, clinician-centric approach to DM self-management.

The results of the current study add to the evidence supporting the effectiveness of group clinics for DM care. In particular, this study highlights the importance of organizing group clinics around theories of goal setting and implementation of behavior change given that prior studies with mixed results focused exclusively on how clinicians create treatment plans with comparatively little attention to how patients integrate effective treatments into everyday actions. Because DM action plans consist of a wide variety of behaviors, group clinic interventions should measure behavioral pro-

Table 2. Comparison of Hemoglobin A\(_1c\) Level and Diabetes Self-efficacy Scale Score by Intervention Group at Each Study Time Point

<table>
<thead>
<tr>
<th>Outcome Measure and Study Time Point (Patients, No.)</th>
<th>EPIC Group Clinic Intervention</th>
<th>Traditional Diabetes Mellitus Group Education</th>
<th>Between-Group Difference</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin A(_1c), level, % of total hemoglobin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (n=87)</td>
<td>8.66 (1.3)</td>
<td>8.74 (1.2)</td>
<td>0.12 (1.25)</td>
<td>.66</td>
</tr>
<tr>
<td>3 mo (n=85)</td>
<td>8.04 (1.35)</td>
<td>8.70 (1.38)</td>
<td>0.60 (1.36)</td>
<td>.03</td>
</tr>
<tr>
<td>1 y (n=85)</td>
<td>8.05 (1.40)</td>
<td>8.64 (1.39)</td>
<td>0.39 (1.39)</td>
<td>.05</td>
</tr>
<tr>
<td>Diabetes Self-efficacy Scale score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (n=87)</td>
<td>7.06 (1.98)</td>
<td>6.64 (2.13)</td>
<td>0.42 (2.06)</td>
<td>.34</td>
</tr>
<tr>
<td>3 mo (n=75)</td>
<td>7.83 (1.19)</td>
<td>7.00 (1.90)</td>
<td>0.84 (1.56)</td>
<td>.02</td>
</tr>
<tr>
<td>1 y (n=76)</td>
<td>7.03 (1.89)</td>
<td>6.40 (1.99)</td>
<td>0.62 (1.94)</td>
<td>.17</td>
</tr>
</tbody>
</table>

Abbreviation: EPIC, Empowering Patients in Care.

*SI conversion factor: To convert hemoglobin A\(_1c\) to a proportion of total hemoglobin, multiply by 0.01.

*aData are presented as means (SDs).*

**Figure 3.** Each data point represents the mean and standard error values for all patients (n=85) at each data collection time point. Using a repeated-measures analysis, the overall effect of the interaction of intervention group by time was significant \( (F_{2,85} = 3.55; P = .03) \) on longitudinal hemoglobin A\(_1c\) values. EPIC indicates Empowering Patients in Care. To convert hemoglobin A\(_1c\) to a proportion of total hemoglobin, multiply by 0.01.
cesses, like self-efficacy, that link clinical outcomes with self-management across heterogeneous action plans. Consistent with prior research, changes in self-efficacy among study participants correlated with effective goal setting and with changes in HbA₁c levels during and after the intervention. Furthermore, the longitudinal analysis adjusting for self-efficacy describes a classic mediation effect for DM self-efficacy in the relationship between EPIC intervention participation and improvements in HbA₁c.

The lack of ongoing improvements in HbA₁c during the follow-up period is disappointing but consistent with findings from prior literature. A meta-analysis of DM self-management interventions found an average HbA₁c improvement of 0.76% after intervention, but this effect declined over time to a minor improvement of 0.26% after 4 or more months after intervention. In contrast, EPIC participants maintained their 0.8% improvement 9 months after intervention. Norris et al. also found that contact time with the DM educator was the best predictor of improvements in glycemic control. Furthermore, highly effective lifestyle interventions for DM include considerably more intensive and prolonged contacts with participants. Booster EPIC session may have produced additional improvement in HbA₁c levels, which is supported by the finding that self-efficacy scores declined without booster sessions. Enhanced training and involvement of PCPs in the EPIC intervention may have also further improved HbA₁c at follow-up. Training of study clinicians consisted of skills development for leading group sessions, mastery of study materials, and strategies for actively engaging patients in treatment planning (see eAppendix for details). The longitudinal success of EPIC will likely require dedicated training time and skills mastery by involved PCPs. In addition, PCPs must be self-aware of the difference between developing a treatment plan and collaborating with patients about the implementation of that plan into daily actions.

Despite these important findings, the current study has limitations. Participation in the study was limited to older veterans receiving primary care in 1 regional VA medical center, which may limit the generalizability of these results. Future studies using a more diverse study sample may enhance the external validity of the EPIC intervention. The pilot nature of this study (sample size, funding, etc.) may have contributed to measurement error and did limit our ability to track clinicians’ responses to action plans and PCPs’ postintervention discussions with study participants; however, the randomization of intervention assignment, persistence of the treatment effect at 1 year, and clinically meaningful effect size should lessen this concern. In addition, the study used a comparative effectiveness design in which the duration of the EPIC intervention sessions exceeded the length of instruction in the traditional groups. However, we note that, with the exception of content on setting goals and formulating action plans, the EPIC group received the same or less content about DM education than the traditional education group. For example, the traditional education group received instruction on details about following diabetic diets that the EPIC group did not. We feel that the extra time allotted to interaction among participants and collaborative work on goal setting more than made up for the relative paucity of content in the EPIC intervention compared with the traditional education intervention. The significant time and effort required by patients and clinicians to attend multiple 2-hour group sessions over a 3-month time frame and the additional training required by study clinicians do limit the generalizability of the EPIC intervention.

Future studies involving the EPIC intervention should compare alternative methods of clinician training and delivery of intervention content. Web- and teleconference-based training and group facilitation may increase the pool of clinicians skilled at group clinic facilitation and the EPIC approach to goal setting. Adaptations to the EPIC design, such as the inclusion of booster sessions, may strengthen the effectiveness of the overall intervention by reinforcing self-efficacy gains and providing further refinement to participants’ action plans. Implementation studies are needed to identify alternative designs that facilitate wider dissemination of EPIC. Such studies could compare the 4-session group clinic model with group plus individual clinic sessions, group plus telephone support, and individual sessions using a “teamlet” model of primary care. Teamlets are the dyad of a PCP and a health educator/coach who performs many of the EPIC intervention activities before and after the PCP visit. The dyadic relationship fosters greater coherence between treatment plan development, setting of self-management goals, and refinements to action plans over time. The dissemination of EPIC using group clinics, teamlets, or some combination will be muted without changes in health insurance financing. Increased support for medical homes and the passage of health care reform may provide the necessary catalyst.

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