Improvements in Patient-Reported Outcomes Associated With an Intervention to Enhance Quality of Care for Rural Patients With Type 2 Diabetes

Results of a controlled trial

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OBJECTIVE — The aim of this study was to examine patient-reported outcomes in a controlled trial of a multifaceted provider-level intervention to improve quality of care for rural patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We conducted a before/after intervention study with concurrent controls in two rural regions in Alberta, Canada. The intervention consisted of six monthly visits by a multidisciplinary health care team and was primarily directed at primary care providers. Clinical and patient-reported outcomes were assessed after 6 months. Patient-reported outcomes included changes in health-related quality of life (Health Utilities Index Mark 3 [HUI3]), satisfaction with care, lifestyle (Diabetes Lifestyle Form), and adherence to self-care activities. Analysis of covariance was used to assess differences over time between the control and intervention regions.

RESULTS — A total of 200 intervention and 172 control subjects were included in this analysis. After adjusting for important clinical and demographic differences, a statistically significant and clinically important improvement in the overall HUI3 score was seen at the 6-month follow-up in the intervention region (0.06 [95% CI 0.02–0.10]) compared with the control region (0.01 [−0.04 to 0.04]) ($P = 0.03$ for the difference between groups). Satisfaction with general medical care ($P < 0.001$ between groups) and diabetes care ($P < 0.001$ between groups) increased among patients in the intervention region compared with the control region. Self-efficacy, attitudes, and beliefs about diabetes control all increased in the intervention region when compared with the control region, but adherence to self-care activities did not.

CONCLUSIONS — A provider-level intervention directed at improving quality of clinical care for patients with type 2 diabetes also had a favorable impact on overall health-related quality of life, satisfaction with care, and other humanistic outcomes.

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Abbreviations: CDA-TDRP, Canadian Diabetes Association Traveling Diabetes Resource Program; DLF, Diabetes Lifestyle Form; HRQL, health-related quality of life; HUI3, Health Utilities Index Mark 3.

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

Type 2 diabetes is a chronic condition that confers a substantial burden on any health care system because of its increasing prevalence and its associated economic impact (1–4). Evidence-based diabetes management that addresses blood pressure, lipids, and glycemic control can reduce morbidity and mortality and may decrease health care costs (5–11). Despite a wealth of evidence, there is growing recognition of treatment gaps in diabetes care when "best practice" is compared with usual care in both urban academic (12–14) and rural settings (15–19).

Interventions aimed at improving the management of diabetes have been somewhat successful in changing the processes for delivering care and have improved intermediate or surrogate outcomes, such as glycemic control. At least one controlled study has demonstrated that comprehensive management of type 2 diabetes can improve both surrogate measures and clinical events (20). Patient-reported outcomes, however, have often been overlooked in the evaluation of such interventions (20,21). In a recent review of 41 studies of community-based controlled interventions to improve processes of care or outcomes in patients with diabetes (21), only four studies evaluated patient-reported outcomes in a manner that would be considered scientifically valid. Furthermore, few patient-reported outcomes other than health-related quality of life (HRQL) were captured (21).

Patient-reported or humanistic outcomes, including HRQL and satisfaction with care, are important to consider because the burden associated with diabetes may extend beyond what is captured by clinical measures. Closing treatment gaps and reaching targets for clinical outcomes often requires more intensive management of diabetes. More intensive management can create an increased sense of

illness burden, and this may result in a net negative impact on HRQL (22) or failure to demonstrate an improvement in HRQL (23–29), despite improvements in clinical measures. Furthermore, physiological measures, such as A1c, do not necessarily reflect how patients feel. The impact of interventions targeted at enhancing the quality of care in diabetes should, therefore, be evaluated broadly and capture these important patient-reported outcomes.

Therefore, when we designed and conducted a controlled trial of clinical quality improvement for rural patients with type 2 diabetes, we ensured that we obtained detailed information about humanistic outcomes in addition to the clinical measurements that were the focus of the intervention (30,31). The clinical outcomes of this trial have previously been reported (31). Our intervention, directed at primary care providers in rural health regions, was associated with trends toward improvement in overall quality of clinical care and a significant improvement in blood pressure management (31). In a prespecified analysis, we hypothesized that our provider-level intervention would also lead to improvements in patient-reported outcomes.

RESEARCH DESIGN AND METHODS

We conducted the Diabetes Outreach Van Enhancement (DOVE) study, a prospective before/after study with concurrent controls, to evaluate a provider-level intervention to improve the quality of clinical care for rural patients with type 2 diabetes. The study design and rationale (30) and clinical results (31) have been previously reported. In summary, two comparable and geographically adjacent rural health regions in Northern Alberta were selected and randomly allocated to intervention or control. The intervention region had a population of 20,000 residents, 17 physicians, and 1 full-time and 2 part-time diabetes educators, whereas the control region had a population of 25,000 residents, 22 physicians, and 1 part-time diabetes educator. Both regions were approximately a 6-h drive from the nearest secondary or tertiary care referral centers. We estimated that ~900 individuals in the control region and 720 individuals in the intervention region would have type 2 diabetes. These approximations were derived using population estimates of the prevalence of diabetes in Alberta (4.0%) and the observation that generally 90% of cases of diabetes in Canada are attributable to type 2 diabetes (32).

Subjects were recruited using identical methods in both regions via referrals from diabetes health care professionals, local pharmacists, primary care physicians, and self-referral. Subjects were included if they had type 2 diabetes, gave informed consent, and had sufficient English literacy to answer questionnaires. We excluded those unable or unwilling to provide consent or individuals with a foreshortened life expectancy. The study was approved by the Health Research Ethics Board of the University of Alberta.

Usual care (control). In the control region, local providers delivered usual care with the addition of three bimonthly visits by the Canadian Diabetes Association Traveling Diabetes Resource Program (CDA-TDRP). The CDA-TDRP travels by van to communities in rural Alberta, raising diabetes awareness and emphasizing patient self-management.

Provider-level intervention. In addition to bimonthly CDA-TDRP visits, the intervention region was exposed to the diabetes outreach service (30,31). The service consisted of a team of specialist physicians, nurse educators, dietitians, and pharmacists. The service traveled to the larger communities in the region on a monthly basis for 6 months, delivering targeted educational messages. Overall, the aim was to promote the concept of vascular health by emphasizing the interaction of blood pressure, cholesterol, and glucose on macrovascular complications of diabetes. These risk factors were promoted because of the availability of effective pharmacotherapies, the cardiovascular risk in diabetes, and their emphasis in clinical practice guidelines (8). Educational messages were delivered, for the most part, by specialist physicians to small groups (i.e., two to six) of primary care physicians, using techniques of group academic detailing (31,33–35). Specific components of the intervention that targeted primary care physicians included small group discussions of real and theoretical cases related to risk factors, delivered by well-known and respected specialists, one-on-one academic detailing by a trained pharmacist, and a referral service for a limited number of patients. In-services were provided for allied health care professionals in groups of 8 to 30. These in-services focused on the importance and management of risk factors. Public lectures focusing on self-management of risk factors were also a component of the intervention.

Measures

To assess the impact of the intervention on patient-reported outcomes, questionnaires were administered at baseline and at 6 months. Questionnaires included demographic and clinical information and self-reported measures of adherence, HRQL, attitudes toward diabetes, and satisfaction with health care. All questionnaires were self-completed and self-reported.

The Health Utilities Index Mark 3 (HUI3) is a preference-based measure of HRQL that uses multiattribute utility theory to assign valuations to different health states (36–38). We previously demonstrated the construct validity of the HUI3 in patients with type 2 diabetes (39). Using the multiattribute approach, health states are defined by a classification system that includes a set of dimensions or attributes of HRQL with a number of different levels for each attribute. In the HUI3 system, eight attributes (including vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) define health status and HRQL. Each attribute has five or six levels, creating 972,000 unique HUI3 health states (37–39). Global scores on the HUI3 range from −0.36 to 1.0 with −0.36 representing the utility of the worst possible HUI3 health state, 0.0 representing dead, and 1.0 representing perfect health (37). Differences of greater than 0.03 for HUI3 overall scores are considered to be clinically important (37,39).

The Summary of Diabetes Self-Care Activities is a 12-item measure of adherence to diet (five items), exercise (three items), blood glucose testing (two items), and diabetes medication activities (two items) (40). In the Summary of Diabetes Self-Care Activities, participants rated either the percentage of time that they adhered to aspects of diet and the number of days or the percentage of time they adhered to exercise recommendations. As recommended by the developers, a *z* score for each self-care activity was then calculated (40).

The Diabetes Lifestyle Form (DLF) is a 20-item questionnaire with three subscales: self-efficacy (five items), beliefs

Table 1—*Baseline characteristics stratified by study group*

	Intervention	Control
n	200	172
Age (years)	63.0 ± 12.7	61.9 ± 12.3
Income (>$40,000 per year) (%)	29.1	22.3
Sex (% male)*	48.7	37.6
Married (%)	70.2	66.1
Aboriginal (%)†	9.5	45.8
Completed high school (%)	35.9	29.2
Duration of diabetes (years)*	7.4 ± 7.8	9.3 ± 9.2
Visited diabetes education clinic (% yes)†	67.4	50.3
Years since last visit (n = 204)	3.4 ± 4.4	4.0 ± 4.6
BMI (kg/m^2)	33.4 ± 7.5	32.1 ± 6.0
Systolic blood pressure (mmHg)	130.2 ± 19.3	133.1 ± 18.0
Diastolic blood pressure (mmHg)†	72.3 ± 11.4	80.1 ± 10.2
Total cholesterol (mmol/l)*	4.86 ± 0.96	5.08 ± 1.03
A1c (%)†	7.17 ± 1.51	7.62 ± 1.73

Data are means ± SD unless otherwise indicated. *P = 0.05; †P < 0.01.

(six items), and attitudes (nine items) toward diabetes (41). Items were scored on five-point Likert scales with higher scores representing more positive attitudes and beliefs toward diabetes and higher self-efficacy in managing diabetes. Items were averaged to create an overall DLF score and five-point subscale scores (41).

Patient satisfaction with their care was assessed using four items: two general items taken from the general satisfaction subscale of the Patient Satisfaction Questionnaire (42) and two analogous items specific to diabetes care. Items were scored on five-point Likert scales and were positively and negatively worded to reduce acquiescent response bias. Each scale (general and diabetes specific) was scored out of 100 points with higher scores reflecting greater satisfaction.

Analysis

Descriptive statistics were used to summarize baseline characteristics of the intervention and control groups. ANOVA and χ^2 tests, as appropriate, were used to determine whether baseline differences between groups on any demographic characteristics, clinical parameters, or patient-reported outcomes were statistically significant.

Change scores were computed for each patient-reported outcome measure from baseline to the follow-up assessment (i.e., 6-month score minus baseline score). Relative changes were compared between the intervention and control regions using baseline-adjusted ANCOVA. Because there were some clinical and demographic differences at baseline between groups, we conducted both unadjusted and adjusted analyses. In one set of analyses, baseline scores for the patient-reported outcome being analyzed were entered as the only covariate to give a more transparent view of the actual data before controlling for other factors. For clarity, these analyses are referred to as "unadjusted." In the second set of analyses, determinants of health were included in the model to adjust for differences between groups. Age, sex, marital status, education, income, aboriginal status, duration of diabetes, and body mass index were controlled to adjust for potential confounding. Baseline scores were also controlled to adjust for initial differences between groups. Clinical parameters that differed between groups, but were unrelated to the patient-reported outcomes, were not controlled for in the analysis. We refer to these analyses as "adjusted," and they are the focus of this report. All analyses were conducted according to the intention-to-treat principle. Specifically, we used a conservative last observation carried forward approach for missing scale scores at the 6-month follow-up. All analyses were conducted using SPSS 11.5 (SPSS, Chicago, IL). We considered a two-tailed P value <0.05 to be statistically significant, did not adjust analyses for multiple testing, and presented estimates of effect with their 95% CI.

RESULTS — A total of 393 (210 intervention and 183 control) individuals with type 2 diabetes were enrolled in the study. This represents ~29 and 20% of individuals with type 2 diabetes in the intervention and control regions, respectively. Of the 393 subjects originally enrolled in the study, 372 subjects (95%) completed baseline patient-reported outcome questionnaires (200 intervention and 172 control group subjects). The 21 subjects who failed to complete baseline questionnaires were younger than those who completed the baseline questionnaire (age 57.1 vs. 62.6 years; P = 0.029) but did not differ with respect to clinical characteristics (e.g., blood pressure, body mass index, A1c, or duration of diabetes). Several of these individuals (n = 12) remained in other components of the DOVE study despite not completing the patient-reported outcomes component.

A total of 322 subjects (82%) completed 6-month follow-up questionnaires (178 intervention and 144 control group subjects). Of the 50 subjects who did not complete follow-up questionnaires, 31 subjects remained in the study and had clinical data available. The remaining subjects prematurely withdrew from the study (n = 18) or were lost to follow-up (n = 1). Reasons for withdrawing were unavailable for the majority (n = 11) of subjects. One subject moved, one subject died, and the remaining subjects (n = 5) declined to continue participation due to time commitment. There were no statistically significant differences observed on baseline demographic and clinical parameters for completers and the 50 noncompleters.

Baseline differences in demographic and clinical characteristics between patients in the intervention and control region were apparent (Table 1). Differences were also observed on a number of the patient-reported measures with patients in the control region reporting significantly lower baseline satisfaction, overall HUI3 scores, and diabetes-related health beliefs.

A statistically significant and clinically important change in HRQL was seen in the overall HUI3 scores from baseline to the 6-month follow-up (Table 2). After adjusting for baseline differences in demographics and clinical variables, essentially no change was observed in the control group (0.01 [−0.04 to 0.04]), whereas the adjusted change observed in the intervention group was relatively large

Table 2—*Unadjusted and adjusted mean change scores (95% CI) from baseline to 6-month follow-up**

Patient-reported outcome	Baseline	Δ_{UNADJ}† (95% CI)	Δ_{ADJ}‡§ (95% CI)	$P\ \Delta_{ADJ}$
HRQ				
HUI3				
Intervention	0.69 ± 0.26	0.02 (−0.03 to 0.03)	0.06 (0.02–0.10)	0.03
Control	0.59 ± 0.32	0.003 (−0.007 to 0.05)	0.01 (−0.04 to 0.04)	
Satisfaction				
Diabetes care				
Intervention	76.4 ± 22.5	3.59 (0.60–6.59)‖	5.27 (1.04–9.51)	0.001
Control	61.8 ± 24.0	−5.61 (−8.90 to −2.31)	−3.67 (−7.80 to −0.46)	
Medical care				
Intervention	77.9 ± 22.0	1.81 (−1.10 to 4.72)‖	3.89 (−0.41 to 8.18)	<0.001
Control	65.9 ± 25.6	−5.93 (−9.17 to −2.70)	−6.56 (−10.73 to −2.39)	
DLF				
Overall				
Intervention	3.75 ± 0.50	0.08 (0.03–0.13)‖	0.06 (−0.02 to 0.14)	0.04
Control	3.67 ± 0.54	−0.04 (−0.10 to 0.02)	−0.07 (−0.15 to 0.02)	
Beliefs				
Intervention	3.70 ± 0.62	0.07 (−0.006 to 0.14)¶	0.09 (−0.02 to 0.19)	0.04
Control	3.49 ± 0.72	−0.05 (−0.13 to 0.36)	−0.05 (−0.16 to 0.05)	
Attitudes				
Intervention	3.82 ± 0.57	0.07 (0.01 to 0.13)¶	0.03 (−0.06 to 0.12)	0.04
Control	3.83 ± 0.60	−0.02 (−0.09 to 0.05)	−0.09 (−0.16 to 0.005)	
Self-efficacy				
Intervention	3.67 ± 0.74	0.13 (0.05–0.22)‖	0.07 (−0.05 to 0.20)	0.03
Control	3.56 ± 0.82	−0.03 (−0.12 to 0.06)	−0.10 (−0.21 to 0.02)	
Summary of diabetes self-care activities				
Diet				
Intervention	−0.025 ± 0.42	−0.03 (−0.08 to 0.03)	0.05 (−0.03 to 0.13)	0.56
Control	0.006 ± 0.47	−0.004 (−0.06 to 0.06)	0.02 (−0.05 to 0.10)	
Exercise				
Intervention	0.12 ± 0.87	−0.11 (−0.20 to −0.02)	−0.09 (−0.23 to 0.05)	0.68
Control	−0.008 ± 0.88	−0.15 (−0.25 to −0.05)	−0.13 (−0.25 to 0.001)	
Testing				
Intervention	−0.035 ± 0.61	−0.07 (−0.15 to −0.002)¶	0.08 (−0.03 to 0.19)	0.06
Control	0.034 ± 0.70	0.05 (−0.03 to 0.13)	−0.05 (−0.15 to 0.05)	
Medication#				
Intervention	0.020 ± 1.01	0.02 (−0.09 to 0.14)	0.11 (−0.07 to 0.28)	0.53
Control	−0.098 ± 0.70	−0.09 (−0.25 to 0.07)	0.17 (0.004–0.34)	

Data are means ± SD unless otherwise indicated. *Analyses were performed according to intent to treat. Last value carried forward imputation was used. †Δ_{UNADJ}, follow-up patient reported outcome minus baseline; adjusted only for baseline differences on patient reported outcome, but not clinical characteristics or demographics. ‡Δ_{ADJ}, follow-up patient reported outcome minus baseline; mean difference adjusted for income, age, BMI, aboriginal status, sex, education, marital status, duration of diabetes, and baseline score. §*n* for adjusted analysis was smaller than unadjusted due to missing data on covariates. ‖$P < 0.01$; ¶$P < 0.05$. #Analysis was performed only for individuals who used oral medication or insulin to manage their diabetes.

(0.06 [0.02–0.10]); the difference in change between groups was statistically significant ($P = 0.03$).

Improvements in all DLF parameters were observed in patients in the intervention region compared with the control region (Table 2). The largest differences in adjusted scores were seen in the beliefs subscale where the intervention regions improved (0.09 [−0.02 to 0.19]) and scores in the control region declined (−0.07 [−0.15 to 0.02]; $P = 0.04$ between groups). A similar pattern was seen for the self-efficacy, beliefs, and attitudes subscales (Table 2).

Satisfaction with general medical care and diabetes care significantly improved in the intervention region and declined in the control region over the study period (Table 2). The adjusted change in satisfaction with diabetes care (5.27 [1.04–9.51]) was larger than that observed for general satisfaction with care (3.89 [−0.41 to 8.18]) in the intervention region. The intervention was not associated with changes in adherence to any of the four diabetes self-care activities (Table 2).

CONCLUSIONS — We previously reported positive overall trends in improving the quality of clinical care of patients with type 2 diabetes with this provider-level intervention (31). In particular, we observed a statistically significant and clinically important improvement in blood pressure levels in the intervention region, although there

was little improvement in cholesterol levels or glycemic control. We also observed trends toward new medication starts in patients in the intervention region. We now report, over the same period of time, significant improvements in a number of patient-reported outcomes. Specifically, in the intervention region, we observed improvements in HRQL and satisfaction with care as well as self-efficacy and attitudes and beliefs toward diabetes.

The change in HRQL over the 6-month study period seen in adjusted HUI3 scores clearly favored the intervention group and exceeded the magnitude of what would be considered clinically important (37,38). Although the HUI3 is not a diabetes-specific measure of HRQL, our previous cross-sectional analyses demonstrated that the HUI3 has discriminative validity in type 2 diabetes (39). Furthermore, the present study was carried out with a control group with adjustments for baseline differences on a number of clinical and demographic variables known to be associated with HRQL, such as education, income, and body mass index (43–45). The presence of a concurrent control group and the ability to adjust our analyses for many potential confounders leads us to conclude that the observed changes in patient-reported outcomes from baseline to follow-up were related to the intervention itself, rather than chance, secular trends, regression toward the mean, or residual confounding.

Satisfaction with general medical care and diabetes care both improved relative to the control region, where satisfaction with care appeared to decline over the same 6-month period. Consistent with the focus of the intervention, it is encouraging to note that the improvement in satisfaction with diabetes care exceeded the improvement with general medical care. It is not clear, however, which aspect of the intervention was associated with change in the satisfaction with diabetes care, given that the intervention was primarily directed at primary care physicians. For example, whereas having access to public lectures on diabetes may have contributed to increased satisfaction with diabetes care, we do not know if patients in the intervention region whose level of satisfaction improved actually attended those lectures. It is possible that greater attention was received as a result of being in the intervention region, which contributed to a perception that care needs were being more fully addressed. Interestingly, in the control region, satisfaction declined during the course of the study. It is possible that this is the natural history of "satisfaction" among rural patients with type 2 diabetes or perhaps the study questionnaires themselves heightened patient awareness of unmet needs in the control region.

There were also small, but statistically significant, improvements in various attitudes and beliefs related to diabetes. It is possible that the intervention induced changes in the practice styles of local providers and that this improved subsequent patient-provider interactions that were perceived by the patients themselves. This conclusion is supported by the concurrent improvements in satisfaction with care in the intervention group described above.

The intervention was not associated with improvements in adherence to various self-care activities. The already high baseline levels of self-reported adherence to certain aspects of the diabetes care regimen, however, may have left little opportunity for improvement. For example, ~95% of intervention group subjects reported that they took all insulin injections as directed in the prior 7 days. Self-reported adherence to oral medications was lower at 81%. Inaccuracy of self-reported adherence may have also been an issue and may have attenuated any opportunity to observe change over time in the intervention or control group. This lack of change in adherence to the self-care activities is not surprising given that targeted patient level lifestyle interventions are needed to improve adherence (20–21); our intervention (directed at metabolic control and medical management) did not provide this.

Whereas the humanistic outcomes in this study were assessed using a before/after design with concurrent controls, this was not a randomized controlled trial, and some limitations for our findings should be noted. We should point out that the random allocation of the two regions to intervention or control condition was not for the purpose of distributing characteristics equally between groups. The purpose of random allocation was, in part, to determine which health region would receive the intervention in a manner that the regions would view as fair. As well, random allocation was used to reduce threats to internal validity that would be created if allocation to intervention or control conditions was intentionally related to study outcomes. Because of the lack of random patient-level allocation, we could not completely control for all preexisting regional trends that might have existed before the first data collection. Indeed, some baseline differences did exist for a number of demographic and clinical characteristics, with the intervention region tending to be consistently favored. Nevertheless, we controlled for all of the potentially confounding variables that we measured, and this adjustment did not materially affect the direction or magnitude of any of our main results.

Second, our sample was a population-based volunteer cohort rather than a true random sample of the population. There is no mechanism in the province of Alberta that would allow us to identify patients with diabetes and contact them for entry into a study. Recruitment strategies and enrollment were similar in both regions, but there may be concern related to "volunteer bias" or the Hawthorne effect. An enthusiastic and enlightened volunteer sample (independent of the intervention) might be expected to be more knowledgeable, more likely to aggressively seek regular medical care, and have greater HRQL or satisfaction with care. In fact, this type of "volunteer bias" would have biased our results to the null, making it difficult to demonstrate any difference between intervention and control regions. Furthermore, local efforts to involve aboriginal people in the study appear to have been stronger in the control region. This resulted in a larger proportion of aboriginal people in the control group despite the aboriginal population being equally represented in both regions. In general, the intervention region was favored on a number of baseline characteristics such as duration of diabetes, total cholesterol, diastolic blood pressure, and A1c. This finding is not surprising given the fact that aboriginal people in Canada tend to have poorer health than the general population (32).

As a further limitation, the 6-month follow-up period for evaluating changes in humanistic outcomes, particularly HRQL, was relatively short. Nonetheless, if our findings are valid, we might expect even greater changes over a longer time horizon. Lastly, as we examined only two northern rural regions in one province,

the results of this study may not be generalizable to the rest of the province or other rural regions.

With these possible threats to validity and limitations in mind, we conclude that a multifaceted provider-level intervention to improve diabetes care in a rural setting was associated with improvements in overall HRQL, satisfaction with care, as well as self-efficacy, beliefs, and attitudes in patients with type 2 diabetes. Interventions such as ours have the potential to improve the quality of diabetes care for patients in rural communities and may provide an alternate means of delivering care in isolated regions. Based on our results and previous systematic reviews (21), we believe that to fully capture the potential benefits (and possible harms) of any intervention strategy directed at patients with diabetes, more attention should be paid to humanistic outcomes.

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