

Compliance with Clinical Practice Guidelines for Type 2 Diabetes in Rural Patients: Treatment Gaps and Opportunities for Improvement

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The level of compliance with clinical practice guidelines for patients with type 2 diabetes was evaluated in 368 patients from two health regions in rural northern Alberta, Canada. Data were collected from patient interviews, drug histories, physical and laboratory assessments, and a self-report questionnaire to assess clinical status, indicators of diabetes management, and health care utilization. Treatment of three clinical indicators of diabetes—hemoglobin A_{1c} (A1C), blood pressure, and low-density lipoprotein cholesterol (LDL)—has been shown to reduce the morbidity and mortality associated with type 2 diabetes. Mean \pm SD values for this cohort of patients were as follows: A1C $7.25\% \pm 1.54\%$, blood pressure $131.7 \pm 18.2/76.2 \pm 12.7$ mm Hg, and LDL 105.2 ± 32 mg/dl. Despite these results, only 10.4% of the patients met all three recommended targets for control of glycemia: A1C below 7%, blood pressure below 130/85 mm Hg, and LDL below 100 mg/dl. Of patients not at target levels, 14.4%, 27.5%, and 86.7% reported receiving no therapy for hyperglycemia, hypertension, and dyslipidemia, respectively. Of those taking oral hypoglycemic agents who were not at target levels, only 35% were receiving combination therapy. Of patients at or above LDL target levels, 87% were not receiving any therapy. Only 22% of patients were taking aspirin, although this therapy would be recommended for the entire cohort according to clinical practice guidelines. Despite the availability of proved effective therapies, treatment gaps were present for this cohort of patients.

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Clinical practice guidelines for management of diabetes mellitus are based in part on the results of randomized, controlled trials. Evidence supports the benefit of lowering the levels of blood glucose, blood pressure, and lipids in patients with type 2 diabetes.^{1–3} Aspirin therapy also has been recommended, with respect to cardiovascular risk reduction.⁴ Aggressive management of diabetes not only should decrease its morbidity and mortality by reducing associated long-term complications but also may significantly decrease costs associated with these complications.^{5, 6} Most morbidity and mortality in patients with type 2 diabetes are associated with macrovascular disease.^{7–11}

The latest version of the Canadian Diabetes

Association's clinical practice guidelines, published in 1998, recommends standards of care for management of diabetes and its complications, such as hypertension and dyslipidemia.⁴ The Canadian guidelines are, for the most part, concordant with United States and European guidelines.¹² However, despite intensive and expensive efforts to disseminate clinical practice guidelines, studies have demonstrated that many physicians do not follow them.^{13–16} Reports have indicated low or variable levels of basic management and preventive services in diabetes care provided by physicians.^{17–19} In evaluations of clinical practice guidelines for diabetes management, low-to-moderate (6–88%) levels of adherence to recommended diabetes practices

were observed,²⁰ although achievement of goals may be more likely in general endocrinology practices.²¹ Concern is increasing regarding access to and quality of diabetes care in rural and underserved areas.²²⁻²⁵

We evaluated the quality of diabetes care in a cohort of patients with type 2 diabetes in rural northern Alberta, Canada. We collected information about clinical status and treatment patterns to assess compliance with the current clinical practice guidelines.

Methods

Study Sample

Patients were recruited for the study by self-referral or referral by local diabetes health care professionals, diabetes education programs, community pharmacists (when dispensing diabetes-related drugs), or primary care physicians. Patients were included in the study if they had type 2 diabetes, lived within the region of interest, gave informed consent, and had sufficient English literacy to answer questionnaires. Patients were excluded if they were unable or unwilling to provide informed consent, had a life expectancy of less than 1 year, or were found not to have type 2 diabetes mellitus. Care providers were drawn from all general practitioners or certified family physicians practicing in the two rural regions. No internists were practicing in these regions. The study protocol was approved by the Health Research Ethics Board at the University of Alberta.

Measurements

Data were collected from laboratory test

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Table 1. Characteristics of the 368 Patients

Characteristic	Years (mean ± SD)
Age	63.4 ± 12.4
Duration of diabetes	8.21 ± 8.53
Time since last diabetes education clinic visit	3.56 ± 4.35
	No. (%) of Patients
Men	161 (43.8)
Smoking history	
Current smoker	64 (17.4)
Past smoker	174 (47.3)
Never smoked	130 (35.3)
Had attended diabetes education clinic	206 (58.7)

results, a self-report questionnaire, and interviews and physical assessments conducted by trained nurses from April–October 2000. Medical charts were not accessed directly. Drug histories were obtained from patients by local study coordinators and checked against local pharmacy records.

Standardized physical assessments were used to record weight, height, and blood pressure. Self-report was used to assess health resource use over the previous 6 months. Health status was assessed with the general health rating question from the 12-item Short-Form Health Survey.^{26, 27} Fasting blood and random urine samples were collected locally but analyzed centrally in one laboratory to determine hemoglobin A_{1c} (A1C) and lipid levels and a random albumin:creatinine ratio.

Data Analysis

All analyses were descriptive; means or frequencies are presented where appropriate. We calculated the frequency of patients who were at treatment target levels: A1C below 7%, determined in the central laboratory, and blood pressure below 130/85 mm Hg, as outlined in the 1998 Canadian clinical practice guidelines.⁴ According to these guidelines, the suggested target levels for plasma lipids depend on individual risk factors (family history of coronary artery disease, smoking, hypertension, low high-density lipoprotein cholesterol level, and age [≥ 45 yrs in men, ≥ 55 yrs in women]). Since family history was difficult to assess, we applied the National Cholesterol Education Program guidelines for target lipid levels—low-density lipoprotein cholesterol (LDL) below 100 mg/dl²⁸—which were identical to Canadian

Table 2. Clinical Indicators in the 368 Patients

Clinical Indicator	Mean \pm SD	Range	Clinical Practice Guideline Target
A1C (%) ^a	7.25 \pm 1.54	3.7–14.9	< 7.0 ⁴
Fasting blood glucose (mg/dl)	145 \pm 38	40–360	72–126 ⁴
Blood pressure (mm Hg)			
Systolic	131.7 \pm 18.2	81–184	< 130 ⁴
Diastolic	76.2 \pm 12.7	50–186	< 85 ⁴
Lipid panel (mg/dl)			
Triglycerides	178 \pm 80	52–392	< 150 ^{28, 29}
LDL	105 \pm 32	18–275	< 100 ^{28, 29}

A1C = hemoglobin A_{1c}; LDL = low-density lipoprotein cholesterol.

^aNormal range is 4.0–6.1%.

Table 3. Achievement of Target Levels for Clinical Indicators in the 368 Patients

Clinical Indicator	No. (%) of Patients	
	At Target	Above Target
A1C < 7% ⁴	183 (49.7)	185 (50.3)
Receiving insulin	24 (24.5)	74 (75.5)
Not receiving insulin	159 (58.9)	111 (41.1)
Blood pressure < 130/85 mm Hg ⁴	168 (45.7)	200 (54.3)
LDL < 100 mg/dl ^{28, 29, a}	142 (41.2)	203 (58.8)

A1C = hemoglobin A_{1c}; LDL = low-density lipoprotein cholesterol.

^aTotal number of patients in the LDL group was 345; LDL values were missing for 23 patients due to nonfasting measurements or elevated triglyceride levels.

provincial guidelines widely disseminated throughout the two regions at the time.²⁹

Results

Three hundred sixty-eight patients (161 men, 207 women, mean age 63.4 \pm 12.4 yrs) with type 2 diabetes were enrolled in the study (Table 1); the overall study design is described elsewhere.²⁶ In this report, only baseline cross-sectional data are presented. The patients had had diabetes for a mean of 8 years; 59% had attended a diabetes education program an average of 3.5 years earlier. At the time of the interviews, 17% of the patients were smokers, 47% had been smokers but had quit, and 35% had never smoked. Patients rated their general health as poor (7.6%), fair (25.5%), good (50%), very good (14.1%), or excellent (2.7%). In the previous 6 months, approximately 50% of physician visits, 20% of visits to emergency facilities, and 40% of days of missed work were reported as attributable to diabetes.

Clinical indicators were, on average, at or near the recommended clinical practice guideline targets (Table 2); 49.7% (24.5% of those receiving insulin), 45.7%, and 41.2% of patients

were at target levels for glycemic, blood pressure, and lipid control, respectively (Table 3). Only 10.4% of patients were at or below target levels in all three areas.

Patients were receiving a mean of 4.9 \pm 3.1 drugs, which consisted of oral antidiabetic agents (61.4% of patients), insulin but no oral antidiabetic drugs (18.2%), antihypertensive agents (62.5%), and lipid-lowering agents (18.2%). Metformin was the most commonly prescribed oral antidiabetic agent (53.2%), followed by sulfonylureas (37.9%) and other agents (8.9%). Patients were receiving a variety of antihypertensive therapies, alone or in combination, most commonly angiotensin-converting enzyme inhibitors (39.7% of patients), calcium channel blockers (16.4%), β -blockers (10.7%), and thiazides (9.1%). Statins were the most commonly prescribed lipid-lowering agents (79.1% of patients). Only 79 (21.5%) of the 368 patients were taking aspirin.

Important therapy gaps were observed in the pharmacologic management in all three clinical target areas for hyperglycemia, hypertension, and dyslipidemia (Table 4). Of 111 patients who were not at the Canadian clinical practice

Table 4. Pharmacologic Management of Clinical Indicators in the 368 Patients

No. of Drugs	Patients Taking Drugs (%)							
	A1C < 7%, ⁴		A1C < 7%, ⁴		Blood Pressure < 130/85 mm Hg ⁴		LDL < 100 mg/dl ^{28, 29, a}	
	Receiving Insulin	Not Receiving Insulin	Receiving Insulin	Not Receiving Insulin	Receiving Insulin	Not Receiving Insulin	Receiving Insulin	Not Receiving Insulin
	At Target	Above Target	At Target	Above Target	At Target	Above Target	At Target	Above Target
0	---	---	37.1	14.4	49.4	27.5	75.4	86.7
1	79.2	64.9	40.9	50.5	26.8	40.5	24.6	12.8
2	20.8	28.4	21.4	28.8	12.5	22.5	---	0.05
3	---	5.4	12.5	6.3	7.7	7.5	---	---
4	---	1.4	---	---	3.6	1.5	---	---
5	---	---	---	---	---	0.5	---	---

A1C = hemoglobin A_{1c}; LDL = low-density lipoprotein cholesterol.

^aTotal number of patients in the LDL group was 345; LDL values were missing for 23 patients due to nonfasting measurements or elevated triglyceride levels.

guideline target for glycemic control (A1C < 7.0%), 14.4% were receiving no therapy, and an additional 50.5% were receiving only one oral agent. Also, 27.5% of patients whose blood pressures were above the target level were not receiving any antihypertensive drugs. Of note, 86.7% of patients whose LDL levels were greater than 100 mg/dl were receiving no lipid-lowering therapy. Across all three target areas, relatively few patients were receiving combination therapies.

Discussion

We sought to determine the quality of care in a cohort of patients with type 2 diabetes in northern rural Alberta, Canada, because of concern that patients living in isolated communities without access to specialists might be at risk of suboptimal care. In fact, we noted that individual target levels for the population were at or near the recommended levels. Nevertheless, we observed several important treatment gaps regarding proved effective therapies.⁴

The greatest treatment gaps were found in the management of cardiovascular risk, such as treatment of dyslipidemia and administration of aspirin; less than 25% of patients were taking aspirin. In almost 60% of patients, LDL levels were above target; this proportion of patients not meeting target is larger than has been observed by others.^{20, 30} In addition, over 85% of these patients were not prescribed any lipid-lowering therapy. Possibly, patients were managed by diet before drug therapy was begun; however, most clinical practice guidelines advise that patients with type 2 diabetes are at very high risk for coronary artery disease and should start receiving drug therapy concurrently with lifestyle

modifications.^{4, 28, 29}

Another plausible reason for inattention to lipid levels may be that physicians are sensitive to the number of drugs these patients already receive (an average of five/patient in our cohort) and hesitate to add another. Furthermore, some physicians may be waiting to see improvements in lipid levels as a result of improvements in glycemic control, although most of our cohort had longstanding diabetes. Emphasis on lowering lipid levels in patients with diabetes is a relatively recent phenomenon,^{3, 31, 32} and physicians may be more inclined to address glycemic and blood pressure control first.

A less obvious but related treatment gap was found in terms of physicians' apparent reluctance to administer combination therapy. Large proportions of patients who did not meet target levels of blood pressure (41% of patients) and glycemic control (51% of those not receiving insulin) were receiving monotherapy. Because these patients began receiving pharmacotherapy, we assumed that diet and exercise therapies were not sufficient. In one British study, most newly diagnosed patients required various therapies to meet glycemic target levels as the study progressed.³³ Less than 55% of patients at 3 years and less than 28% of patients at 9 years randomized to any monotherapy could maintain an A1C level less than 7%.³³

A survey in a large U.S. medical group found that for most patients whose A1C levels were above target, pharmacotherapy was not changed even after laboratory work was available.³⁴ The patients in northern rural Alberta had had diabetes for an average of 8 years, so we presumed that many of them probably needed combination therapy. However, many apparently had reached a "treatment cap" for monotherapy

(i.e., a limit to the number of drugs physicians were willing to prescribe) and were not prescribed combination therapy.

In terms of glycemic control, metformin was the most commonly prescribed antidiabetic agent. Since many of our study patients were overweight, metformin would have been the most appropriate therapeutic agent for them.³⁵ This situation is representative of the market for oral antidiabetic agents in Canada, where metformin leads in number of such prescriptions. However, the situation is quite different in the United States, where more widespread prescribing of metformin is limited by the concern of lactic acidosis in patients with renal or cardiac failure. Evidence covering 3 decades of experience in Canada and Europe suggests that this risk is minimal.³⁶ Despite clear contraindications, metformin apparently continues to be safely administered, even in patients with mild renal or cardiac failure.³⁷ Furthermore, in a recent epidemiologic study, we provided strong evidence to support the safety of metformin in overall management of type 2 diabetes.³⁸

Strengths of our study are its relatively large numbers and its comprehensive and detailed collection of various indicators of health status and quality of care. Few rigorous studies of patients with diabetes living in rural areas have been conducted. Nevertheless, several limitations should be noted. Our data were cross-sectional. We used primarily self-reported data from a possibly nonrepresentative (volunteer) sample. The data may have been biased, limited by requesting information for only the preceding 6 months. Although self-reported data previously have overestimated adherence to guidelines,³⁹ in our patient cohort we found that self-reporting of drugs taken was reliable when compared with formal drug histories ($\kappa = 0.76\text{--}0.93$).⁴⁰ Also, the cross-sectional nature of these data does not allow us to determine if the patterns of care have changed over time. Thus, it may be difficult to interpret the relation between drugs taken and levels of metabolic control.

The near-target mean results for glycemic, blood pressure, and lipid control could be related to the fact that the study patients were volunteers. We estimated that our sample represented 20% of all people with diabetes in the two rural health regions that we studied. Volunteer study patients may be more willing than other patients to manage their diabetes and maintain their health status; if so, any treatment

gaps observed in this sample would be even more pronounced in the nonvolunteer population.

The patients' health care providers were not recruited for this study. In addition, the health care system is public and universal, with no predetermination, incentive, or rules dictating that particular patients be assigned to particular physicians. Therefore, it can be assumed that the care provided by the patients' physicians was not significantly different from that of other physicians in the rural regions.

Three recent reports from large U.S. medical centers suggest that treatment gaps exist in their patient populations with type 2 diabetes, with undertreatment of hypercholesterolemia and hypertension.^{41–43} These reports indicate similar levels of guideline compliance in terms of achievement of clinical targets in patients during approximately the same time period. In a review of patients with type 2 diabetes undergoing cardiac catheterization, less than 1% had optimal control of all modifiable risk factors, which consisted of the same three clinical indicators as in our study (blood pressure, A1C, and lipid levels) plus body mass index, smoking, and aspirin intake.⁴³ Many reasons can account for this lack of compliance, and although guidelines imply that 100% compliance constitutes good care, some authors have questioned that thinking and instead want more realistic clinical targets.^{44, 45} We agree that target levels must be realistic in the context of contemporary clinical practice; however, the current practice patterns seem far below optimal.

In the two rural health regions we studied, specialist care was available only at distant centers. Several U.S. reports suggest that quality of care for patients with diabetes and compliance with guidelines are suboptimal in rural areas.^{22–25} A recent U.S. study of 30,589 Medicare patients determined that larger rural towns, however, were likely to provide the best conditions for high-quality care.⁴⁶ This care was provided by generalists, however, who are more likely to be internists in the United States rather than family physicians, as in Canada. An estimated 1.3–2.4% increase in the number of primary care physicians and 1.0–6.6% increase in specialists would be required to meet practice guidelines in rural areas.²² However, it clearly is not just differences in physician specialty that result in the gaps in care for patients with diabetes. Rather, factors contributing to these gaps occur at three levels: health care providers, patients, and the health care system.^{21, 47} Development of

quality-improvement initiatives²⁴ and use of technology²⁵ have been proposed as possible solutions to help close these gaps.

Conclusion

We found that the quality of care for patients with diabetes in northern rural Alberta, Canada, is similar to that of comparable North American populations studied in other rural settings—or even urban settings—particularly regarding blood pressure and lipid management. Nevertheless, there is substantial room for improvement, especially in terms of achieving various clinical targets by administering combinations of drugs rather than monotherapy.

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