Controlled Trial of a Multifaceted Intervention for Improving Quality of Care for Rural Patients With Type 2 Diabetes

OBJECTIVE — Despite good evidence and clinical practice guidelines, studies document that treatment of type 2 diabetes is less than optimal. Lack of resources or limited access may put patients in rural communities at particular risk for suboptimal care.

RESEARCH DESIGN AND METHODS — We conducted a prospective, before/after study with concurrent controls to assess the effectiveness of a multidisciplinary diabetes outreach service (intervention) for improving the quality of care for rural patients with type 2 diabetes. Our intervention consisted of six monthly visits by a traveling team of specialist physicians, nurses, dieticians, and a pharmacist. The core of this service was specialist-to-rural primary care physician academic group detailing. Two comparable regions in Northern Alberta were randomly allocated to control or intervention. Data were collected before and 6 months after intervention in a representative volunteer sample. The primary outcome was a 10% improvement in any one of the following: blood pressure, total cholesterol, or HbA1c.

RESULTS — Our analysis included 200 intervention and 179 control subjects; 14 subjects were at all three primary outcome targets at baseline. The intervention was associated with a trend toward improvement in primary outcome at 6 months (42% intervention vs. 25% control, P = 0.004); however, there were only small, nonsignificant changes in total cholesterol or HbA1c. The intervention was associated with a significant increase in satisfaction with diabetes care. Multivariate adjustment for baseline differences between intervention and control subjects did not affect any of the main results.

CONCLUSIONS — A diabetes outreach service has the potential to improve the quality of diabetes care for rural patients. Future studies need to involve longer timelines and larger sample sizes.

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RESEARCH DESIGN AND METHODS — We conducted a prospective before/after study with concurrent controls to evaluate a diabetes outreach service (the Diabetes Outreach Van Enhancement [DOVE] intervention). The study design and rationale are described in detail elsewhere (20). 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 25,000 residents, 17 physicians, and one part-time diabetes educator, whereas the control region had a population of 25,000 residents, 22 physicians, and one part-time diabetes educator. Both regions were about a 6-h drive from the nearest secondary or tertiary care referral centers.

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 individuals unable or unwilling to provide consent or with shortened life expectancy.

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

DOVE intervention In addition to bimonthly CDA-TDRP visits, the intervention region was exposed to the diabetes outreach service (see online appendix [available at http://care.diabetesjournals.org]) (20). The service consisted of a team of specialist physicians, nurse educators, dieticians, and pharmacists. The service traveled to the largest 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 burden of macrovascular disease in people with diabetes, the availability of effective therapies, and their emphasis in the CDA clinical practice guidelines (8). Educational messages were delivered, for the most part, by specialist physicians to small groups of primary care physicians (i.e., two to six), using techniques of group academic detailing (24–26). The study pharmacist also met with all local primary care physicians for one-on-one academic detailing. All intervention physicians were exposed to at least 50% of these visits.

Measurements The primary outcome measurement was improvement in the care of patients with diabetes. We defined this as a 10% improvement over baseline in any one of the following after 6 months: blood pressure, total cholesterol, or HbA1c (20). This is consistent with previous Canadian work by Sibley et al. (27), who considered at least a 10% improvement in processes of care to be the minimal clinically important difference for similar sorts of interventions. We evaluated changes in each separate component as our three-prespecified secondary outcomes. Given the necessarily short time frame of our study, we did not consider it reasonable or likely to attempt to change the proportion of subjects who achieved recommended targets. Furthermore, aggressive management to achieve recommended targets in such a short time frame might result in untoward consequences, such as serious hypoglycemic episodes or serious orthostasis (20). Our interest was in important changes in risk factors from baseline.

As additional indicators of quality, we examined changes in target medications, i.e., medications used for lowering blood pressure, cholesterol, and glucose levels. We included among our patient-reported outcomes two items of general satisfaction with medical care (28) and two parallel items on general satisfaction with diabetes care. Both two-item scales were summed and converted to percentage scores.

Baseline data were collected by interviews, physical assessments, laboratory testing, and self-report questionnaires. Six trained study coordinators conducted interviews and collected information, including demographics, histories, and detailed medication profiles. Standardized physical assessments were used to record weight, height, and blood pressure. Fast-ing blood samples were collected locally but analyzed centrally in one laboratory to determine HbA1c and cholesterol levels. Subjects were followed-up 6 months after study entry, at which time all the aforementioned measurements and questionnaires were repeated. Local coordinators and primary care physicians could not be blinded to allocation status because the randomization was by rural health region.

Sample size considerations and analysis The primary outcome was defined as the proportion of subjects achieving a 10% improvement in any one of the following: blood pressure, total cholesterol, or HbA1c. The primary analysis used a $\chi^2$ test, and we calculated $P$ values, odds ratios (ORs), and 95% CIs. The unit of analysis was the patient. Subjects already at or below clinical targets (blood pressure <130/80 mmHg, total cholesterol levels <4.0 mmol/L, and HbA1c <11.5% of upper limit of normal) at baseline were excluded from the primary analysis. Because patients saw multiple providers within the region, as well as specialists at distant referral centers, we were not able to adjust analyses for the possibility of provider-level statistical clustering. We estimated 300 subjects in total would provide at least 80% power to detect any difference >10% in the primary outcome between study arms (20). Additional recruitment to a target of 400 subjects was planned to provide additional power for evaluation of secondary outcomes and allow for losses to follow-up and drop out.

To address potential imbalances in prognostically important baseline characteristics, multivariate logistic regression was also used. The dependent variable in these models was achievement of a 10% improvement for each individual. Independent variables were intervention status, baseline blood pressure, total cholesterol, HbA1c, and other statistically or clinically significant covariates (e.g., age, female sex, indigenous status, marital status, duration of diabetes, and target medications). The same analytic approach was applied to each of the components of the primary outcome. Changes in patient satisfaction were compared between regions using ANCOVA, again adjusting for any baseline differences and potential confounding variables. All analyses were intention to treat.
RESULTS — A total of 393 (210 intervention and 183 control) individuals with type 2 diabetes were enrolled. The control group had more women, more indigenous people, longer duration of diabetes, and lower baseline satisfaction (Table 1). There were differences in clinical indicators, with the control group having higher diastolic pressure, total cholesterol, and HbA1c (Table 1). Forty subjects (10%) dropped out, died, or were lost to follow-up, 14 (7%) in the intervention region and 26 (14%) in the control region. Other than a longer duration of diabetes (13.5 vs. 7.8 years), there were no differences between those who completed the study and those who did not.

Although clinical indicators were, on average, at or near the recommended targets at baseline (Table 1), the percentage of subjects actually at target for blood pressure, cholesterol, and glycemia were 46, 41, and 50%, respectively. Only 14 (4%) subjects were at or below all three targets and were excluded from further analysis. The final sample included 200 intervention-region subjects and 179 control-region subjects.

In the intervention region, 44% of subjects achieved a 10% improvement in the primary outcome by 6 months compared with 37% in the control region (OR 1.32, 95% CI 0.87–1.99; \( P = 0.19 \)) (Fig. 1). When individual components of the primary outcome were considered, we observed significant improvements in blood pressure levels, with little change in total cholesterol or HbA1c (Fig. 1). In the intervention region, 51 of 122 (42%) subjects above 130/80 mmHg at baseline had a 10% improvement in blood pressure compared with 30 of 122 (25%) in the control region (2.20, 1.30–2.80; \( P = 0.0001 \)).

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Table 1—Baseline characteristics, stratified by intervention and control status

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
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<tbody>
<tr>
<td>n</td>
<td>210</td>
<td>183</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63.9 ± 12.7</td>
<td>62.0 ± 12.4</td>
</tr>
<tr>
<td>Sex (% male)†</td>
<td>48.7</td>
<td>37.6</td>
</tr>
<tr>
<td>Married (% †</td>
<td>66.7</td>
<td>55.6</td>
</tr>
<tr>
<td>Indigenous (%)†</td>
<td>9.6</td>
<td>46.6</td>
</tr>
<tr>
<td>Completed high school (%)</td>
<td>35.7</td>
<td>29.0</td>
</tr>
<tr>
<td>Duration of diabetes (years)†</td>
<td>7.4 ± 7.8</td>
<td>9.4 ± 9.2</td>
</tr>
<tr>
<td>Years since last visit? (n = 204)</td>
<td>3.4 ± 4.4</td>
<td>4.0 ± 4.6</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>33.5 ± 7.4</td>
<td>33.1 ± 9.1</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>130.4 (19.0)</td>
<td>132.2 (18.2)</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)†</td>
<td>72.5 (11.4)</td>
<td>79.7 (10.4)</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)*</td>
<td>4.87 (0.94)</td>
<td>5.08 (0.98)</td>
</tr>
<tr>
<td>HbA1c (%)*</td>
<td>7.17 (1.48)</td>
<td>7.59 (1.67)</td>
</tr>
<tr>
<td>Satisfaction with medical care (0–100)†</td>
<td>77.9 (22.0)</td>
<td>65.9 (25.6)</td>
</tr>
<tr>
<td>Satisfaction with diabetes care (0–100)†</td>
<td>76.4 (22.5)</td>
<td>61.8 (24.0)</td>
</tr>
</tbody>
</table>

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

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Figure 1—Percentage of subjects achieving improvement (i.e., ≥10% change) in quality of diabetes care, stratified by intervention and control status.
Quality improvement for rural diabetes care

Table 2—New medication starts for individuals above target at baseline

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any target medication</td>
<td>50 (25.0)</td>
<td>42 (23.5)</td>
<td>0.73</td>
</tr>
<tr>
<td>Blood pressure lowering</td>
<td>21 (17.2)</td>
<td>18 (14.8)</td>
<td>0.60</td>
</tr>
<tr>
<td>Cholesterol lowering</td>
<td>12 (6.8)</td>
<td>6 (3.8)</td>
<td>0.21</td>
</tr>
<tr>
<td>Glucose lowering</td>
<td>13 (13.4)</td>
<td>9 (8.2)</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Data are n (%).

0.004). For total cholesterol, 23 of 176 (13%) intervention subjects versus 27 of 160 (17%) control subjects achieved a 10% improvement (P = 0.33 for difference); for glucose control, 17 of 97 (18%) in the intervention region versus 15 of 110 (14%) in the control region had a 10% improvement in HbA1c (P = 0.44 for difference).

Controlling for baseline differences in demographic and clinical characteristics with multivariate regression did not materially alter these results. The adjusted OR for the primary outcome was 1.04 (95% CI 0.64–1.70). The likelihood of patients in the intervention region achieving a 10% improvement in blood pressure remained statistically significant (2.22, 1.25–3.96). The OR for improved total cholesterol and HbA1c was not significantly different between regions. One-quarter of all subjects had new target medications started during the 6-month follow-up (Table 2), and compared with the control region, there were nonsignificant, absolute increases in starting medications for blood pressure (3%), cholesterol (3%), and glucose (5%).

Concordant with changes in the primary outcome and medication starts in the intervention region, we noted significant improvements in satisfaction with medical care in general and specifically with diabetes care among patients enrolled in the intervention region compared with the control region. Adjusted mean change scores for the intervention and control subjects on the two satisfaction scales were 4.1 vs. −11.9 (P < 0.001) for general medical care, respectively, and 4.1 vs. −3.7 (P = 0.008) for satisfaction with diabetes care, respectively.

**CONCLUSIONS** — We found that, compared with usual care, a diabetes outreach service directed at primary care physicians improved the quality of diabetes care for rural patients. Within 6 months, there were trends toward improvement in diabetes care, as indicated by changes in blood pressure, total cholesterol, and glucose levels. We observed a 7% absolute improvement (19% relative improvement) in our composite diabetes quality-of-care indicator. Furthermore, we noted a statistically significant and clinically important 17% absolute improvement (68% relative improvement) in blood pressure levels in the intervention region compared with the control region. Conversely, exposure to the diabetes outreach service was associated with little change in cholesterol or glucose levels. Consistent with the main study findings, we noted small, but nonsignificant, increases in the starting of medications for the control of blood pressure, cholesterol, and glucose in the intervention region.

Most of the improvements that we observed were in blood pressure control, which is arguably the component of diabetes care that has the greatest weight of evidence in terms of the clinical benefits that accrue with optimal treatment (6,9). It may also be argued that treating blood pressure was the easiest quality indicator to address, given that hypertension management is among the most common reasons for adults to visit their doctor. Furthermore, given the short duration of follow-up, there was likely insufficient time for the trends of increased target medication use to translate into measurable differences in cholesterol and glucose.

Interestingly, it appeared that the diabetes outreach service also improved subjects’ satisfaction with the care they received, whereas subjects in the control region became less satisfied. This was true of both medical care in general and specifically with the care they received for their diabetes. Despite the intervention being targeted at health professionals, observed changes in processes of care were apparent to and appreciated by the subjects themselves. This is an important observation because it is an indicator of quality of care (29) and also because satisfaction with care is associated with more positive health behaviors, including adherence to medical recommendations (29–31).

Although there were multiple components to our intervention, the primary method was delivery of evidence-based messages by specialist physicians using group academic detailing. Academic detailing is one of the few consistently successful methods of changing physician practice that is available (24,25). Group detailing is a proven, effective modification of this technique whereby small groups of primary care physicians are detailed together (26). We recruited locally well-known clinical experts ("opinion leaders"), instructed them in methods of detailing, helped them develop educational messages and detailing materials, and then had them travel to rural regions and interact in person with small groups of rural physicians. They were accompanied by a multidisciplinary team of allied health professionals who interacted with their respective professional counterparts.

To better put our results in context, we relied extensively on the conclusions of a recently published systematic review and methodologic critique of 41 diabetes-specific interventions in community settings that was conducted by Renders et al. (21). They concluded that multifaceted interventions do lead to improvements in diabetes process indicators but that not enough attention had been paid to patient-centered outcomes. Furthermore, they observed that most interventions studied evaluated only changes in glycemic control and strongly recommended that future studies address changes in overall cardiovascular risk and changes in patient-centered outcomes (21). We believe our study overcomes some of the limitations of previous research. For example, Renders et al. (21) found that many diabetes-related interventions were evaluated using designs that lacked rigor, such as the uncontrolled before/after study. This commonly used study design is prone to numerous forms of bias (24,25). We tested our intervention using a much more rigorous quasi-experimental design, the before/after study with concurrent controls. Our specific study design, although not a cluster randomized controlled trial, is of suffi-
icient validity that it could be included in a systematic review from the Cochrane Library Effective Practice and Organization of Care (EPOC) Group (32). By using a rigorous and valid design, assessing within-person change over time, and evaluating in multiple clinical and humanistic outcomes, we found that our results support our original hypotheses.

Nevertheless, this was a not a randomized controlled trial, and so there are alternate explanations and limitations for our findings. First, we only collected data at two time points (before and after intervention) in two only roughly comparable regions. Our study cannot completely control for preexisting regional trends that might have existed before the first data collection. These preexisting secular trends in clinical practice are one of the major threats to the validity of uncontrolled studies (25). For instance, without a control region, we would have claimed a 42% absolute improvement in blood pressure levels with our intervention; however, there was a concomitant 25% improvement in the control region. Nonetheless, physicians in the intervention region may have already been more aggressive in their practices regarding blood pressure treatment than control physicians, and over 6 months it could be posited that all we observed was a reflection of a trend that predated our intervention. Baseline blood pressure control was similar between regions, however, and we adjusted for any baseline differences; this would control (to some extent) differences in regional practice style.

Second, our findings, particularly with respect to blood pressure control, could be a result of measurement bias. Local study coordinators collected all of our data and were not (and could not be) blinded to allocation status. Although this is less of an issue for the laboratory measurements of cholesterol and HbA1c, it may be a threat to the validity of our conclusions regarding improvements in blood pressure. However, similar data collection methods were applied in both regions, and at the time of the follow-up visits, six different study coordinators undertook measurements without referring to baseline measurements. Furthermore, although not statistically significant, other measurements that were relatively free from bias (e.g., changes in HbA1c, satisfaction, and direction of all target med-

cation starts) were positively associated with the intervention.

In addition to these potential threats to validity, some other limitations of this study should be noted. Ideally, our patients should have been a representative random sample of the diabetic population in the two regions, rather than the population-based volunteer cohort we assembled. There is no mechanism in the province of Alberta that would allow us to identify diabetic patients and contact them for entry into a study. Nevertheless, recruitment strategies and enrollment were similar in both regions, and 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 more adherent to medications. In fact, this type of volunteer bias would have biased to the null, making it difficult for us to demonstrate any difference between intervention and control. In an analogous fashion, since the control region physicians were to some degree aware that an intervention was taking place, they may have altered their practice; again, this would tend to bias toward finding no effect of the intervention.

Our sample only provided enough power to detect 10% changes in a number of intermediate outcomes; we did not have sufficient power to examine clinical end points, such as decreases in myocardial infarction or diabetes-related hospitalizations. Furthermore, the time horizon for evaluating changes in the processes of care was relatively short. It is possible that a longer follow-up period may have revealed sustained improvements in the clinical outcomes or increased use of targeted medications. On the other hand, decay in the short-term enhancements in quality of care may have resulted with the completion of the intervention. We have therefore planned a longer-term follow-up of study participants in which all clinical indicators (i.e., process and intermediate outcomes) will be assessed again after 18 months. This follow-up study is ongoing. Lastly, we examined only two northern rural regions in one province, and our results may not be generalizable. Ideally, a quality improvement intervention such as this would have studied more regions, with cluster random allocation to intervention or control.

With these possible threats to validity and limitations in mind, we conclude that a multifaceted diabetes outreach service (that includes specialist-to-generalist group academic detailing) has the potential to improve the quality of diabetes care for patients in isolated rural communities. Promising strategies, such as the one described in this report, need to be developed, adequately funded, and rigorously evaluated. Future research efforts should be directed at larger samples, at more rural communities, and studied over a longer period of time.

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