Can J Diabetes 40 (2016) 120–125

Contents lists available at ScienceDirect

Canadian Journal of Diabetes

journal homepage: www.canadianjournalofdiabetes.com

Original Research

The Need Associated with Diabetes Primary Care and the Impact of Referral to a Specialist-Centered Multidisciplinary Diabetes Program (the NADIR Study)

Harpreet S. Bajaj MD, MPH [a,*], Ronnie Aronson MD [b], Karri Venn RD [b], Chenglin Ye MSc [b,c], Maha E. Sharaan MD, MSc [b]

[a] LMC Diabetes & Endocrinology, Brampton, Ontario, Canada
[b] LMC Diabetes & Endocrinology, Toronto, Ontario, Canada
[c] Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada

ARTICLE INFO

Article history:
Received 3 April 2015
Received in revised form
14 July 2015
Accepted 16 July 2015

Keywords:
diabetes management
cardiovascular risk factors management
goal achievement
primary care
specialist care

ABSTRACT

Objective: The impact of specialist care on glycemia and cardiovascular risk factors in patients with diabetes is uncertain. This observational cohort study investigated metabolic risk factors in patients referred to LMC Diabetes & Endocrinology for diabetes management.
Methods: The cohort included 306 consecutive patients with diabetes referred to LMC in Ontario between January and June 2010. Sources of prereferral data included consultation notes, records from primary care physicians and the Ontario Lab Information System. Postreferral data were obtained from LMC's patients' records.
Results: The mean duration of diabetes before referral was 11 years, and the mean baseline glycated hemoglobin (A1C) level was 8.8%. Among patients with uncontrolled A1C levels at baseline, 73% had had no A1C values ≤7% for up to 6 years before referral. Following referral, mean A1C levels decreased to 7.8% at 6 and 12 months (both $p<0.001$ vs. baseline). Attendance at diabetes education programs improved from 28% to 67% postreferral, and attendees achieved significantly greater A1C reductions than nonattendees (mean 1.1% vs. 0.7%, respectively).

Mean low-density lipoprotein levels declined from 2.3 mmol/L at referral to 1.8 mmol/L at 12 months ($p<0.05$). Mean blood pressure was similar, at 128/75 before and 129/75 mm Hg after referral; however, following referral, blood pressure improved from 143/89 to 134/80 ($p<0.001$) in patients with previously uncontrolled blood pressure. Use of guideline-recommended medications increased significantly following referral.
Conclusion: Referral to specialist care should be considered early in the course of diabetes in order to optimize management of glycemia and cardiovascular risk factors.
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Mots clés :
la gestion du diabète
cardiovasculaires gestion des facteurs de risque
réalisation des objectifs
soins primaires
soins de spécialiste

RÉSUMÉ

Objectif : On ignore l'incidence des soins de spécialiste sur la glycémie et les facteurs de risque cardiovasculaire chez les patients souffrant de diabète. La présente étude de cohorte (observationnelle) examinait les facteurs de risque métabolique chez les patients orientés pour une prise en charge du diabète au LMC Diabète & Endocrinologie.
Méthodes : La cohorte comptait 306 patients consécutifs souffrant de diabète qui étaient orientés vers un centre LMC en Ontario entre janvier et juin 2010. Les sources de données pré-aiguillage étaient les suivantes: les notes de consultation, les dossiers provenant des médecins de soins primaires et le Système d'information de laboratoire de l'Ontario. Les données post-aiguillage étaient tirées des dossiers des patients des LMC.
Résultats : La durée moyenne du diabète avant l'aiguillage était de 11 ans, puis la concentration initiale moyenne de l'hémoglobine glyquée (A1c) était de 8.8%. Parmi les patients ayant des concentrations initiales d'A1c non maîtrisée, 73% n'avaient obtenu aucune valeur d'A1c ≤7% jusqu'à 6 ans avant l'aiguillage. Après

* Address for correspondence: Harpreet S. Bajaj, MD, MPH, 2130 North Park Drive, Suite 238, Brampton, Ontario L6S 0C9, Canada.
E-mail address: harpreet.bajaj@lmc.ca

1499-2671 © 2016 Published by Elsevier Inc. on behalf of Canadian Diabetes Association.
http://dx.doi.org/10.1016/j.jcjd.2015.07.004

l'aiguillage, les concentrations moyennes d'A1c diminuaient à 7.8% à 6 et à 12 mois (les deux p<0.001 *vs* au début). La participation aux programmes d'enseignement sur le diabète grimpait à 67% après l'aiguillage contre 28% avant l'aiguillage, et les participants obtenaient des réductions significativement plus grandes de l'A1c que les non-participants (moyenne de 1.1% *vs* 0.7%, respectivement). Les concentrations moyennes de lipoprotéines de basse densité baissaient de 2.3 mmol/l au moment de l'aiguillage à 1.8 mmol/l à 12 mois (p<0.05). La pression artérielle moyenne était similaire, soit 128/75 avant l'aiguillage et 129/75 mm Hg après l'aiguillage. Cependant, après l'aiguillage, la pression artérielle passait de 143/89 à 134/80 (p<0.001) chez les patients ayant une pression artérielle auparavant non maîtrisée. L'utilisation de médicaments recommandés par les lignes directrices augmentait significativement après l'aiguillage.
Conclusion: L'aiguillage vers les soins de spécialiste devrait être considéré dès le début du diabète afin d'optimiser la prise en charge de la glycémie et des facteurs de risque cardiovasculaire.
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Introduction

Diabetes mellitus is a chronic metabolic condition that is attaining epidemic proportions in Canada and around the globe. Long-term uncontrolled hyperglycemia is associated with multiple microvascular and macrovascular complications, which are preventable with effective goal-based medical care (1–6).

In Canada, primary care physicians (PCPs) bear most of the responsibility for managing diabetes, particularly in patients with early type 2 diabetes. However, 3 separate Canadian data surveys published within the past 10 years (7–9) have shown that most patients managed in primary care do not achieve the glycemic control targets recommended by the Canadian Diabetes Association. Following the successful reduction in cardiovascular risk and mortality achieved by a multipronged specialist-led approach in the Steno-2 trial (10), which included control of glycemia, hypertension and dyslipidemia, smoking cessation and consideration of cardioprotective medications; such a multifactorial, comprehensive cardiovascular disease risk management intervention can be considered essential for patients with diabetes (11). However, effective reduction of these risk factors has not been achieved at the population level, neither in Canada (9) nor in the United States (12).

Information about referral patterns of patients with diabetes by PCPs, and the impact of integrated team-based, specialist-led care models in achieving better clinical outcomes, is scarce and equivocal (13–15). Hence, the Need Associated with Diabetes Primary Care and the Impact of Referral to a Specialist-Centered Multi-disciplinary Diabetes Program (NADIR) study was conducted to compare glycemia and cardiovascular risk factor management before and after PCP referral to LMC Diabetes & Endocrinology (LMC). This "real-life" observational cohort study also aimed to characterize the impact of improvements in diabetes education and pharmacotherapy changes on metabolic risk factor control following management by a specialist physician at LMC.

Methods

Clinic patients

LMC is a multisite, community-based, specialist-led, referral-based, multidisciplinary program that uses a single electronic medical record across its sites. For the purposes of this review, referrals to approximately 20 diabetes specialist physicians working at 7 Ontario-based LMC clinics within the Greater Toronto Area, which has a total population of 6.5 million, were eligible. Patients with type 1 or type 2 diabetes who were referred to LMC between January 2010 and June 2010 were eligible for inclusion in this observational cohort study. Exclusion criteria included: 1) referral by a doctor other than a PCP; 2) referral for a nondiabetes diagnosis; 3) past history of specialist physician treatment for diabetes at LMC or elsewhere; 4) newly diagnosed diabetes (<6 months duration); 5) a minimum of 2 prior visits with their PCPs, including A1C or lipids assessments, within 1 year before specialist referral, and at least 1 follow-up clinic visit with an LMC specialist physician ≥3 months after the initial consultation; 6) age younger than 18 years or older than 75 years; 7) severe renal insufficiency (estimated glomerular filtration rate <30 mL/min/1.73 m^2 at referral); 8) documented history of severe hypoglycemia or a documented less aggressive diabetes control goal; 9) enrolment in an LMC research protocol with an investigational therapy and 10) patient-signed consent form for inclusion in queries. An independent healthcare professional, who was blinded to the study hypothesis and design, examined all consecutive patient referrals between January and June 2010 and applied the above prespecified inclusion and exclusion criteria to determine eligibility.

Data collection and statistical analysis

Patient referrals were identified from the LMC referral database and anonymized such that subsequent identification was based solely on the patient's assigned number and initials. All patient confidentiality principles of Personal Health Information Protection Act were followed. Historical laboratory results for up to 10 years prior to the referral date were downloaded from the Ontario Lab Information System or retrieved from PCP records. The study was approved by the Research Ethics Review Board, IRB Services.

Study data are presented as means for continuous variables and as percentages for categorical variables. Comparisons between PCP care before referral and specialist care after referral were made using paired t tests or Wilcoxon rank sum tests for non-normally distributed data to find continuous variables. For categorical data, comparisons were made by using chi-square tests. Subgroup analyses of medication use within the cohort were performed using the McNemar test. All analyses were performed using SAS v. 9.2 software (SAS, Cary, North Carolina, United States), and p values <0.05 were considered statistically significant.

Results

A total of 2914 screened consecutive subjects met the broad inclusion criteria. The following reasons were given for exclusion of subjects by the blinded chart reviewer: 841 (32%) subjects were excluded because of incomplete data prior to referral or for referral by non-PCPs or for nondiabetes diagnoses; 708 (27%) subjects were excluded because of incomplete data postreferral or enrolment in another investigational therapy study; and 642 (24%) subjects were excluded because of historical consultation with a diabetes specialist physician prior to LMC referral or referral for newly diagnosed diabetes (≤6 months' duration). Other prespecified criteria accounted for the remaining 417 (16%) exclusions of subjects. Thus, the final NADIR cohort for analysis included 306 subjects (47% female, mean age 58 years). The mean duration of diabetes at the time of referral was 11 years, and only 28% of the cohort had received formal diabetes education prior to referral. Previous diabetes

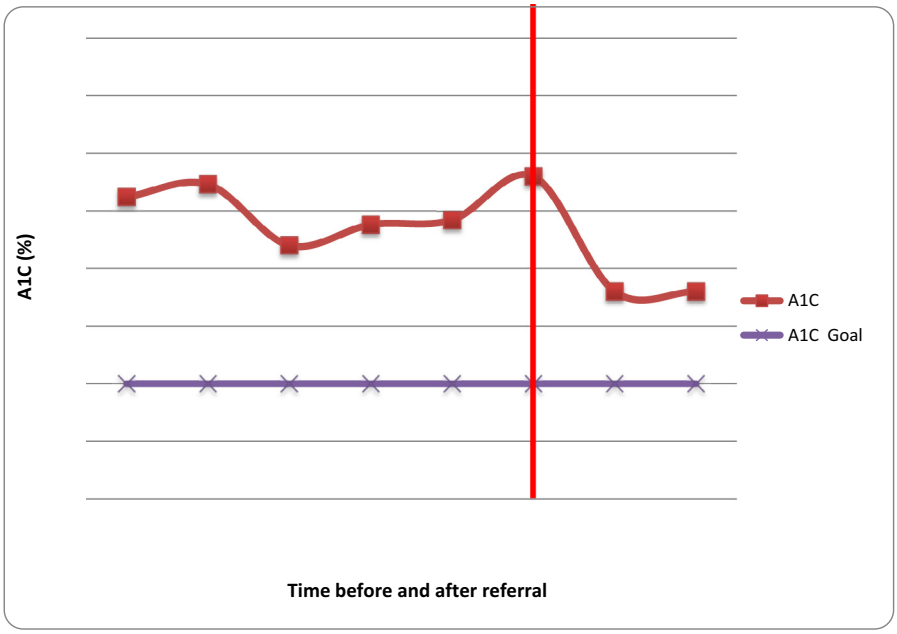

Figure 1. Mean (SD) A1C among NADIR cohort prior to and after referral to LMC Diabetes and Endocrinology. *NADIR,* Need Associated with Diabetes Primary Care and the Impact of Referral to a Specialist-Centered Multi-disciplinary Diabetes Program; *SD,* standard deviation.

education varied across the Greater Toronto Area, ranging from 8% in the city of Brampton to 50% in the community of Thornhill.

Glycemic control before and after referral

Figure 1 shows mean A1C levels during prereferral periods of up to 5 years and during the 12 months after referral. The mean baseline levels of A1C in the full cohort (n=306) was 8.8%, and they were 9.2% in the subgroup of patients (n=258) who were referred with uncontrolled A1C levels (>7%) at baseline. Of these latter patients, 189 (73%) had never had controlled A1C values (≤7%) prior to specialist referral.

Following referral, mean A1C levels were reduced to 7.8% at both 6 and 12 months, representing a 1.0% reduction from baseline ($p<0.001$). Among the patients with uncontrolled A1C levels at baseline (mean=9.2%), the A1C levels were reduced to a mean of 8.0% at 6 months and 12 months after referral ($p<0.001$). The proportion of patients who achieved target glycemic control (A1C ≤7%) increased from 13% at baseline to 31% during the 12-month postreferral period, while the proportion with poor glycemic control (A1C >9%) decreased from 42% at baseline to 18% after 12 months ($p<0.001$). Overall, 46% of patients achieved at least 1 value of A1C level ≤7% during the 12 months following specialist referral.

Diabetes education program attendance

Overall, 59% of patients attended the LMC diabetes education program, and in this subgroup, the mean reduction in A1C levels at 12 months was significantly greater than in those who did not attend the program (Figure 2); (mean 1.1% vs. 0.7%; $p<0.001$). Similarly, the mean reduction in A1C levels was significantly greater in the 40% of patients who were using insulin before or after referral than in nonusers (Figure 2); (1.1% vs. 0.8%; $p<0.001$). Furthermore, there was a significant interaction between insulin usage and program attendance. Among insulin users, the subgroup that also attended the program showed A1C level reductions of 1.2% at 12 months, compared with only 0.5% in those who did not attend ($p=0.017$). Similar differences between insulin users and nonusers were seen irrespective of prereferral program attendance, although the differences were not statistically significant due to smaller sample sizes of these subgroups (prior attendees: 1.2% in insulin users vs. 0.4% in nonusers; nonattendees: 1.2% vs. 0.5%, respectively).

Antihyperglycemic agent prescriptions

Progression in antihyperglycemic agent prescriptions after LMC referral are presented in Table 1. Even in a subgroup of patients with type 2 diabetes taking noninsulin therapies, in whom no change in the number of oral antihyperglycemic agents was made, a significant postreferral reduction in A1C levels of 0.7% was observed. The mean number of oral antihyperglycemic agents prescribed per patient increased from 1.6 at baseline to 1.9 at 12 months after referral ($p<0.001$). The proportion of patients on the following medications increased significantly ($p<0.001$) at 12 months postreferral compared to baseline: metformin (91% vs. 82%); dipeptidyl peptidase 4 (DPP-4) inhibitors (35% vs. 7%); glucagon-like peptide 1 (GLP-1) receptor agonist (10% vs. 0) and basal insulin (21% vs. 5%). The proportion of patients taking glyburide was reduced to 12% at 12 months postreferral compared to 31% at baseline.

Additional cardiovascular risk factors and evidence-based medication prescriptions

Changes in other cardiovascular risk factors before and after referral are summarized in Table 2. Among patients with type 2 diabetes whose baseline LDL cholesterol (LDL-C) levels were uncontrolled (mean=3.0 mmol/L), the mean level achieved was 2.0 mmol/L at 12 months after referral ($p<0.001$). The mean number of cholesterol-lowering medications increased from 0.85 per patient at baseline to 1.0 at 12 months postreferral ($p<0.001$), with a significant increase in prescriptions for statins (Table 2). The proportion of patients receiving a second cholesterol-lowering agent was very low and did not change significantly during the 12 months after referral. The mean number of blood pressure-lowering medications increased from 1.5 per patient at baseline to 1.7 by the end of the 12-month postreferral period ($p<0.001$). The proportion of subjects taking

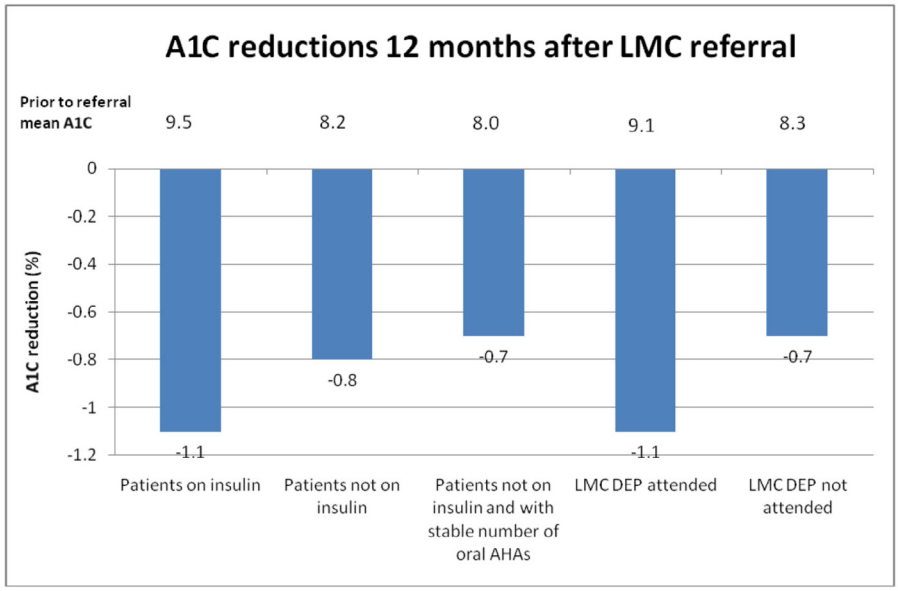

Figure 2. Reduction of A1C levels in patient subgroups. *AHA*, antihyperglycemic agents; *DEP*, Diabetes education program; *LMC*, LMC Diabetes & Endocrinology.

Table 1
Progression of antihyperglycemic therapy after referral to an LMC Diabetes & Endocrinology specialist

Prior to referral (n)	6 months after referral						12 months after referral					
	No OAHA	1 OAHA	2 OAHAs	3 OAHAs	3+OAHAs	Insulin	No OAHA	1 OAHA	2 OAHAs	3 OAHAs	3+OAHAs	Insulin
No OAHA (18)	53%	33%	0	0	0	13%	25%	42%	0	17%	0	17%
1 OAHA (51)	2%	40%	22%	26%	4%	6%	0%	27%	22%	29%	12%	10%
2 OAHAs (66)	0	6%	36%	21%	21%	15%	0	4%	18%	24%	33%	22%
3 OAHAs (78)	0	3%	5%	35%	20%	38%	0	3%	3%	35%	22%	37%
3+OAHAs (30)	0	0	3%	23%	37%	37%	0	4%	0	24%	20%	52%

OAHA, oral antihyperglycemic agent (including GLP-1R agonist); OAHAs were counted only in patients not taking insulin.

Table 2
Cardiovascular risk factor management before and after referral to LMC Diabetes & Endocrinology

	Proportion of patients on statin Rx	Mean LDL-C (mmol/L) in full cohort	Proportion of patients on RAAS Rx	Mean SBP/DBP (mm Hg) in full cohort	Mean SBP/DBP (mm Hg) among uncontrolled BP cohort[b]
Prior to referral	74%	2.3	67%	128/75	143/89
12 months postreferral	92%[a]	1.8[a]	78%[a]	129/75	134[a]/80[a]

DBP, diastolic blood pressure; *RAAS*, renin-angiotensin-aldosterone system; *SBP*, systolic blood pressure.
[a] p<0.005.
[b] SBP >130 mm Hg or DBP >80 mm Hg at baseline.

agents blocking the renin-angiotensin-aldosterone system (Table 2) as well as diuretic therapy increased (31% at baseline to 38% postreferral for diuretics [p=0.02]). The proportion of patients receiving calcium channel blockers changed nonsignificantly (23% at baseline vs. 26% postreferral; p=0.09).

Proportion of patients reaching targets among patients uncontrolled at baseline

Among the 258 patients with type 2 diabetes whose A1C levels were uncontrolled at baseline (A1C >7%), the proportion whose A1C levels had improved to ≤7% following referral was 30.2% at 6 months and 31.2% at 12 months. Similarly, among the 145 patients with type 2 diabetes whose baseline LDL-C levels were uncontrolled (LDL-C>2 mmol/L); the proportion in whom LDL-C improved to ≤2.0 mmol/L postreferral was 42.8% and 63.6% at 6 and 12 months, respectively. Among the 113 patients with type 2 diabetes whose systolic blood pressure was uncontrolled at baseline (>130 mm Hg), the proportion whose systolic blood pressure improved to ≤130 mm Hg postreferral was 55.8% at 6 months and 57% at 12 months.

Conclusions

This "real-life" NADIR cohort study, based in urban Canadian communities, has documented changes in diabetes management following specialist referral in a large cohort of patients in whom control of metabolic risk factors had not been achieved during continuing management in primary care. Overall, the results of this study emphasize the need for early and comprehensive diabetes-management strategies with multidisciplinary approaches involving diabetes specialists and certified diabetes education programs for patients with diabetes.

The prereferral data in NADIR confirm previous survey reports (7–9) that a significant proportion of patients with diabetes in Canada may not be meeting the glycemic targets recommended by

current national guidelines. However, the true magnitude of average A1C elevation at the population level in Canada is unclear from the available literature because a wide variety of ranges has been reported—from a mean A1C of 7.3% to 7.4% reported in Diabetes in Canada Evaluation (DICE) (7) and the more recent Diabetes Mellitus Status in Canada (DM-SCAN) (9) studies to a mean A1C of 8.9% observed in the Canadian cohort of the global Study of Once Daily Levemir (SOLVE) (13). This discrepancy is probably explained by a number of differences in the data-collection methods employed and the study population characteristics in our study compared to the published literature. The NADIR study cohort had a longer mean duration of diabetes (11 years), compared with 6 to 9 years in the DICE, Diabetes Registry to Improve Vascular Events (DRIVE), and DM SCAN studies. Furthermore, the NADIR study patients had been referred to specialist clinics by their PCPs for diabetes management and may, therefore, represent a more challenging patient population than those included in previous studies. However, it should also be pointed out that the 3 cross-sectional studies (DICE, DRIVE and DM-SCAN) were based on survey-based data collection, hence allowing for the possibility that selection bias influenced the average A1C levels; e.g. selection of PCPs by invitation, low PCP survey participation rates (65% in DM-SCAN [9]) as well as discretionary selection of patients by PCPs.

Many studies (14–17) have suggested "clinical inertia" in primary care as a central reason for poor goal achievement in diabetes. The NADIR study results add to this literature by documenting a significant "referral inertia" among PCPs, which results in delayed referrals to specialists and diabetes education programs despite long-term poor A1C control. This delay in referral was observed even among PCPs in urban Canadian communities and despite unrestricted availability of specialists. The present study corroborates previous findings that suggest that less than one-third of patients with diabetes attend diabetes education programs in Canada (18,19). Diabetes self-management education has been proven to enhance self-care behaviours and to affect outcomes (20–22). In the present NADIR study, the LMC diabetes education program was associated with a significant reduction in A1C levels, irrespective of prior attendance or insulin use, even among those patients in whom the use of oral antihyperglycemic agents did not change. Previous studies have indicated that early specialist referral is the strongest predictor of the quality of diabetes care (14,15,23,24). In addition to better glycemic control, our study shows significant improvements in cardiometabolic risk factors and improved use of evidence-based cardiometabolic medications following specialist referral. The observed improvements in A1C, LDL-C and blood pressure levels in NADIR would be expected to translate into significant reductions in the microvascular and macrovascular complications of diabetes to a degree similar to that observed in the landmark Steno-2 clinical trial (10), in which continuity of care was shared with specialists. Indeed, in a recently published population-based propensity-score matched cohort study using provincial health data from Ontario, Booth et al conclude that early endocrinologist care is associated with lower incidences of cardiovascular events and death in patients newly diagnosed with diabetes who have comorbid medical conditions (25).

We believe that the real-world retrospective data collection in the NADIR study provides a powerful tool for investigating the standards of prior-to-specialist care provided by PCPs and the subsequent impact of specialist intervention. The thorough approach to data collection (multiple data gathering approaches—chart audits, Ontario Lab Information System and direct requests to PCPs) is a strength of the study. However, the postreferral improvements seen in NADIR may not be generalizable to all patients; 1) patients who may be nonadherent to appointments; and 2) patients who decline to be referred for specialist care altogether. The NADIR study's observational design may be considered an additional limitation; however, the prespecified inclusion and exclusion protocol, the study enrolment eligibility assessment by a blinded healthcare professional, the rigorous data collection methods employed, and the consistent metabolic improvement observed after specialist referral suggest that confounding and bias are unlikely to have affected the conclusions of the NADIR study in a significant manner. A randomized controlled trial may be conceptualized to address the NADIR hypothesis, but is likely to suffer from biases introduced by the use of nonblinded physicians, as well as imbalances in crossover and in lost-to-follow-up among the randomized trial arms. An additional limitation of the NADIR study is that some subgroup analyses may be subject to type 1 statistical errors because of limited sample size. Finally, the follow-up period after specialist referral was limited to 12 months, precluding conclusions about long-term patient outcomes.

The NADIR study has important implications from a public health perspective. We suggest that referral to an integrated diabetes care centre that follows a team-based treatment model, including both a specialist physician and a diabetes education program, may help to delay or prevent disease progression and the development of diabetic complications. Over time, the growing public expenditure associated with complications would be reduced by decreases in the number of hospital visits and admissions, medical procedures and interventions, sick days and time off work due to illness and medical appointments. Analysis of an Ontario-specific model of diabetes care suggests that multidisciplinary programs would be cost-effective for the treatment and management of adults with type 2 diabetes (26). Our observations of the degree of referral inertia and the impact of specialist intervention on improved goal achievement, call for a change from the traditional, sequential approach to diabetes care toward shared care models, with the specialist integrated in the healthcare team early in the course of diabetes in order to improve goal-based management, delay disease progression and prevent complications.

Acknowledgements

We thank Dr. Hertzel Gerstein MD, MSc, FRCPC (McMaster University, Hamilton, Ontario, Canada); Dr. Ronald Goldenberg, MD, FRCPC, FACE (LMC Diabetes & Endocrinology, Thornhill, Ontario, Canada) and Dr. Robert Schlosser, MD, FRCPC (LMC Diabetes & Endocrinology, Thornhill, Ontario, Canada) for their reviews and provision of comments on the manuscript. Editorial assistance in the development of this article was provided by Dr. Michael Shaw (MScript Ltd, Hove, United Kingdom).

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