Diabetes guidelines: easier to preach than to practise?

A retrospective audit of outpatient management of type 1 and type 2 diabetes mellitus

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ABSTRACT

Objective: To review the management of glycaemia, blood pressure and serum lipids in a hospital outpatient diabetes clinic, the director of which co-authored the current national diabetes management guidelines.

Design: Retrospective audit.

Setting: Outpatient diabetes clinic in a tertiary referral teaching hospital, Sydney, NSW.

Study population: 96 patients with type 1 diabetes (mean age, 44.4 [SD, 12.8] years) and 509 patients with type 2 diabetes (mean age, 64.4 [SD, 12.0] years) attending the clinic in 2003, who had undergone formal review of complications.

Main outcome measures: Weight, height, control and treatment of glycaemia, blood pressure and serum lipids, and prevalence of diabetic microvascular complications.

Results: Glycated haemoglobin (HbA_{1c}) was < 7% in 13% of type 1 and 30% of type 2 diabetes patients, and > 8% in 47% and 34%, respectively. 35% of patients with type 1 diabetes and 71% of patients with type 2 diabetes were treated with antihypertensive agents. Of these patients, 29% and 24%, respectively, had blood pressure readings ⩽ 130/80 mmHg. Among patients not treated with hypertensive agents, blood pressure readings were ⩽ 130/80 mmHg in 60% of type 1 and 38% of type 2 diabetes patients. About 30% of patients with type 1 diabetes and 50% of those with type 2 diabetes were being treated with lipid-lowering agents; of these, about 60% had low-density lipoprotein (LDL) cholesterol levels < 2.6 mmol/L. Among patients not treated with lipid-lowering agents, about 40% had LDL cholesterol levels < 2.6 mmol/L. Retinopathy was documented in 52% and 18%, and nephropathy in 9% and 36% of type 1 and type 2 diabetes patients, respectively.

Conclusions: Despite the demonstrated benefits of tight glucose, blood pressure and lipid control in reducing the risk of macrovascular and microvascular complications in type 1 and type 2 diabetes, our results suggest that treatment targets are not being met in a large proportion of patients attending a tertiary referral hospital. Responsible practice suggests that treatment targets and the current means to achieve them should both be examined.

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The number of adults with diabetes worldwide is predicted to increase from 135 million in 1995 to 300 million in 2025.[1] Diabetes is associated with a significantly increased risk of mortality, predominantly from cardiovascular disease.[2] Intensive treatment of glycaemia, blood pressure and serum lipids has been shown to delay the onset and progression of complications in type 1 and type 2 diabetes.[3-9] Similarly, intensive intervention targeting multiple risk factors reduces the risk of cardiovascular disease and microvascular complications both effectively and significantly in individuals with type 2 diabetes.[10] Despite widespread reporting of these trial findings, their incorporation into clinical guidelines and subsequent implementation in routine practice is a challenge, with treatment targets sometimes unrealistic and difficult to meet.[11] This is evidenced by a recent study of the management of type 2 diabetes in an urban Australian community, which reported that very few patients achieve recommended targets for glycaemic control.[12]

The aim of this audit was to review the outpatient management of glycaemia, blood pressure and lipids in a Sydney teaching hospital and to assess whether current treatment targets were being met. This is of particular interest as the director of the diabetes centre at this hospital (LVC) has co-authored diabetes management guidelines for general practitioners,[13] and both senior authors (DJC and LVC) have published recommendations for diabetes management.[14]

METHODS

Study population

The study population included adult patients attending the weekly outpatient diabetes clinic at St Vincent's Hospital, Sydney, NSW. All patients with type 1 and type 2 diabetes who had a formal complication review in 2003 were included in this study.

The clinic is conducted on a weekday morning and is attended by six doctors (comprising consultant endocrinologists and endocrine and diabetes registrars), a diabetes nurse educator and a pharmacist. A dietitian is also available for consultation but does not routinely attend the clinic. On average, patients with type 1 diabetes attend the clinic two to four times per year, and patients with type 2 diabetes are reviewed 6–12 monthly. Formal complication screening reviews are conducted and recorded at intervals of 12–18 months, with complication screening forms completed at the time of consultation by the treating physician.

Data collection

We retrospectively collated and analysed 12 months of data on weight, height, and control and treatment of glycaemia, blood pressure and lipids from the complication screening forms. The data were extracted from the forms and entered into a database by a clinical nurse consultant in diabetes (WB).

Of an estimated 950 patients attending the clinic in 2003, 605 had complication screening forms completed, comprising 96 patients with type 1 diabetes and 509 with type 2 diabetes.

Weight and height were checked by the clinic nurses, and body mass index (BMI) was calculated as weight divided by height squared (kg/m^2). Blood pressure was recorded by the consulting physician with the patient in the sitting or supine position, using a cuff size appropriate for the patient.

Glycated haemoglobin (HbA_{1c}) was generally measured on the day of complication review in the outpatient clinic, with the result available within 15 minutes (upper limit of normal, 6.0%). Lipid levels were checked before or at the time of

1 Demographic and body mass index characteristics of patients included in the audit

	Type 1 diabetes ($n = 96$)	Type 2 diabetes ($n = 509$)
Mean age (years) (SD)	44.4 (12.8)	64.4 (12)
Number of males (%)	45 (47%)	316 (62%)
Mean duration of diabetes (years) (SD)	22.9 (13.5)	10 (8.8)
Smokers (%)	14%	14%
Body mass index*		
$< 25\ kg/m^2$ (normal)	33 (44%)	43 (11%)
$25–29.9\ kg/m^2$ (overweight)	31 (41%)	120 (32%)
$\geq 30\ kg/m^2$ (obese)	11 (15%)	215 (57%)

* Data were available for 75 patients with type 1 diabetes and 378 with type 2 diabetes. ◆

complication review. Data from microvascular complication screening was also obtained.

Treatment targets

American Diabetes Association (ADA) treatment targets available in the year of the survey were:

- $HbA_{1c} < 7\%$;
- Blood pressure < 130/80 mmHg (with pharmacological treatment indicated if systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg); and
- Serum levels of low-density lipoprotein (LDL) cholesterol < 2.6 mmol/L, triglycerides < 1.7 mmol/L and high-density lipoprotein (HDL) cholesterol > 1.1 mmol/L.[15]

RESULTS

Demographic and BMI characteristics of patients included in this audit are shown in Box 1.

Diabetes management

Patients with type 2 diabetes were treated with: diet alone, 62 (12%); oral agents alone, 296 (58%); oral agents and insulin, 87 (17%); and insulin alone, 64 (13%).

Of patients with type 1 diabetes with complete data, 32% had consulted a diabetes educator in the previous 2 years and 17% a dietitian. Proportions were similar among those with type 2 diabetes (31% and 20%, respectively). Antiplatelet agents were taken by 21% of those aged over 50 years with type 1 diabetes and 59% of those aged over 50 years with type 2 diabetes.

Glycaemic control

HbA_{1c} values satisfied the ADA target of < 7% in only 12 of 89 patients with type 1 diabetes (13%) and 144 of 476 patients with type 2 diabetes (30%) in whom results were available. HbA_{1c} was > 8% in 42 (47%) and 162 (34%) of those with type 1 and type 2 diabetes, respectively.

Blood pressure control

Data on blood pressure treatment and control were available in over 90% of patients with complication reviews. Antihypertensive treatment was being used by 35% of those with type 1 and 71% of those with type 2 diabetes. Among those with type 1 diabetes receiving antihypertensive treatment, the treatment comprised one agent for 26 patients (84%), two agents for four patients (13%) and three agents for one patient (3%). Corresponding figures in patients with type 2 diabetes were 205 (60%), 118 (35%) and 17 (5%), respectively.

Among those treated, blood pressure readings were at or below the ADA target of 130/80 mmHg in nine of those with type 1 diabetes (29%) and 82 of those with type 2 diabetes (24%). Among patients not receiving antihypertensive medication, blood pressure was ≤ 130/80 mmHg in 34 of those with type 1 diabetes (60%) and 53 of those with type 2 diabetes (38%).

2 Proportion of patients with diabetes achieving glycaemic and blood pressure targets in selected published surveys

Study and year	Population	Setting	Percentage with $HbA_{1c} < 7\%$	Blood pressure	
				Target (mmHg)	Percentage achieving target
Current study (2003)	Type 1 diabetes Type 2 diabetes	Sydney teaching hospital	13% 30%	≤ 130/80	29% (treated); 60% (untreated) 24% (treated); 38% (untreated)
ANDIAB (2004)[17]	Patients with diabetes (98% adult)	Australian diabetes centres	38%*	< 130/80	32% (39% aged < 60 years; 25% aged > 60 years)
AusDiab (1999–2000)[18]	Type 2 diabetes	National population-based survey	78% (diet) 50% (OHA only) 24% (insulin)	< 140/90	32% (treated), 55% (untreated)
NHANES (1999–2000)[19]	Adults with diabetes	National population-based survey	37%	< 130/80	36%
New Mexico study (1999–2000)[20]	Adults with diabetes	Managed care organisation	37%	< 130/80	29%
National Diabetes Audit UK (2003–2004)[21]	All patients with diabetes	Health care sector audit	23% (56%)†	< 135/75	21%
Swedish study (2003)[22]	Type 2 diabetes	National diabetes register	58%‡	< 130/80 ≤ 140/85	13% (10% of treated patients) 50% (43% of treated patients)

Target glycated haemoglobin (HbA_{1c}): * ≤ 1% above upper limit of normal range. † < 6.5% (≤ 7.5%). ‡ < 7.3%. ANDIAB = Australian National Diabetes Information Audit and Benchmarking. AusDiab = Australian Diabetes, Obesity and Lifestyle Study. NHANES = National Health and Nutrition Examination Survey. OHA = oral hypoglycaemic agents. ◆

3 Recommended low-density lipoprotein (LDL) cholesterol treatment targets in patients with diabetes

	Diabetic patients in whom drug (statin) treatment indicated	LDL treatment target
American Diabetes Association (2005)[35]	Patients > 40 years with total cholesterol ≥3.5 mmol/L (consider drug treatment in high-risk patients aged < 40 years)	< 2.6 mmol/L (< 1.8 mmol/L in those with established cardiovascular disease)
National Cholesterol Education Program (NCEP) Adult Treatment Panel III (2001, 2004)[36,37]	LDL cholesterol ≥ 3.4 mmol/L (optional for LDL cholesterol 2.6–3.3 mmol/L)	< 2.6 mmol/L (< 1.8 mmol/L in those with established cardiovascular disease)
Diabetes Australia Guideline Development Consortium (type 2 diabetes) (2004)[13]	LDL cholesterol > 2.5 mmol/L	≤ 2.5 mmol/L
National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand (type 2 diabetes) (2005)[38]	LDL cholesterol > 2.5 mmol/L	< 2.5 mmol/L (< 2.0 mmol/L in high-risk patients with coronary heart disease)
The Practical Implementation Taskforce for the Prevention of Cardiovascular Disease (2004)[28]	Total cholesterol > 3.5 mmol/L	Not stated
Third Joint Task Force of European and other Societies on Cardiovascular Disease Prevention in Clinical Practice (2003)[29]	Total cholesterol ≥ 5 mmol/L or LDL cholesterol ≥ 3 mmol/L	< 2.5 mmol/L
Joint British Societies (2005)[16]	All patients ≥ 40 years; patients aged 18–39 years with associated risk factors*	< 2.0 mmol/L (or 30% reduction from baseline, whichever is lower absolute value)
British Hypertension Society (2004)[31]	Patients with hypertension and type 2 diabetes aged up to at least 80 years with total cholesterol ≥ 3.5 mmol/L	< 2.0 mmol/L (or 30% reduction from baseline, whichever is lower absolute value)

* At least one of the following: retinopathy (pre-proliferative, proliferative, maculopathy), nephropathy, glycated haemoglobin (HbA_{1c}) > 9%, hypertension, total cholesterol ≥ 6 mmol/L, features of the metabolic syndrome, first-degree relative with premature cardiovascular disease. ◆

Lipid control

Total cholesterol levels and information about treatment with lipid-lowering agents were recorded in 51 patients with type 1 diabetes and 335 patients with type 2 diabetes. Of these, 16 (31%) and 177 (53%), respectively, were being treated with lipid-lowering agents. Among patients with type 1 diabetes, 10 treated patients (63%) and 29 untreated patients (83%) had total cholesterol levels < 5.5 mmol/L. Corresponding figures for those with type 2 diabetes were 144 (81%) and 111 (70%), respectively.

Of the patients described above, LDL cholesterol levels and information on treatment with lipid-lowering agents were available in 35 type 1 and 235 type 2 diabetes patients. Among patients with type 1 diabetes, six of the 10 treated patients (60%) and nine of the 25 untreated patients (36%) had LDL cholesterol levels < 2.6 mmol/L. Results were similar in type 2 diabetes: 73 of 125 treated patients (58%) and 44 of 110 untreated patients (40%) had LDL cholesterol levels < 2.6 mmol/L.

Of the patients with data available, HDL cholesterol level was ≥ 1.0 mmol/L in about 90% of patients with type 1 diabetes and 70% of patients with type 2 diabetes, irrespective of treatment status. Triglyceride levels were within target (< 1.7 mmol/L) in more than 80% of type 1 and about 40% of type 2 diabetes patients with results available.

Microvascular complication screening

Over 95% of the total cohort had the results of a recent retinal examination recorded (most frequently with an ophthalmologist), with documented retinopathy in 49 of those with type 1 diabetes (52%) and 88 of those with type 2 diabetes (18%).

Among 51 patients with type 1 diabetes and 301 with type 2 diabetes who were known to have been tested for nephropathy, 9% and 36%, respectively, had microalbuminuria or proteinuria (urinary albumin to creatinine ratio > 2.5 mg/mmol if male or > 3.5 mg/mmol if female and/or 24-hour urine albumin excretion > 30 mg). Of the 44 male patients with type 1 diabetes and the 249 male patients with type 2 diabetes with data recorded, erectile dysfunction was reported by 10 (23%) and 140 (56%), respectively.

DISCUSSION

Despite strong evidence that intensive control of cardiovascular risk factors reduces morbidity and mortality in type 1 and type 2 diabetes, our study of an outpatient diabetes clinic population revealed that a large number of patients were not achieving recommended treatment targets.

Over the past two decades, large, prospective, randomised studies have incontrovertibly demonstrated that intensive glycaemic control in patients with type 1 and type 2 diabetes delays the onset and progression of microvascular complications, such as retinopathy, nephropathy and neuropathy, and that glucose-lowering with metformin reduces the risk of macrovascular disease events in overweight patients with type 2 diabetes.[3,5,6] Furthermore, in the Epidemiology of Diabetes Interventions and Complications (EDIC) Study, it was recently reported that, after 17 years of follow-up, participants with type 1 diabetes who previously had been treated intensively with insulin in the Diabetes Control and Complications Trial (DCCT) had a 42% lower risk of cardiovascular disease events compared with patients who previously had been treated conventionally.[4] Given this strong evidence base, the ADA has recommended a target HbA_{1c} of < 7%,[15] and the new Joint British Societies' guidelines (JBS 2) published in December 2005 recommended a

target HbA_{1c} of < 6.5%.[16] As highlighted by our study and other studies reported in the literature,[17-22] these targets are increasingly difficult to achieve (Box 2).

When interpreting our results, it is important to appreciate that HbA_{1c} values in the clinic population described in this study are likely to be skewed to higher values, as the clinic population comprises mainly patients referred by general practitioners with poorly controlled or newly diagnosed type 1 and type 2 diabetes, or those recognised to have complications. Therefore, the study population represents a select group of patients, and our results may not be representative of patients with diabetes in the wider Australian community.

Our results should also be considered in the context of the findings of the United Kingdom Prospective Diabetes Study (UKPDS), in which median HbA_{1c} values over 10 years were 7% in the intensively treated group.[5] This result indicates that half of the intensively treated patients failed to achieve this glycaemic target, despite their participation in an intensive-treatment diabetes study. It is therefore not surprising (and perhaps even encouraging) that 30% of patients with type 2 diabetes in our clinic population had an HbA_{1c} < 7%. It should also be noted that, although about half of the participants with type 1 diabetes in the intensive arm of the DCCT achieved an $HbA_{1c} \leqslant 6.05\%$ one or more times during the study, fewer than 5% of participants maintained an average value below this target, despite an intensive effort with full resources, expert staff and patient compliance.[3] Nonetheless, our results illustrate that, with currently available therapies, many patients fail to reach recommended treatment targets. Indeed, clinicians appreciate that, for many patients, individualised recommendations may be more appropriate.[23]

The UKPDS also demonstrated that "tight" blood pressure control delayed the development and progression of macrovascular and microvascular disease in type 2 diabetes.[7] It is important to note that, despite participation in a clinical trial, only 56% of patients in the "tight control" group and 37% in the "less tight control" group achieved a blood pressure < 150/85 mmHg. More recently, the Heart Outcomes Prevention Evaluation (HOPE) Study Investigators reported that patients with diabetes and at least one other cardiovascular risk factor (not necessarily hypertension) treated with the angiotensin-converting enzyme inhibitor ramipril were less likely to develop the composite endpoint of myocardial infarction, stroke or death from cardiovascular disease, compared with those who received placebo, despite a mean reduction in blood pressure of only 3/2 mmHg.[24] Guidelines from the ADA published at the beginning of the year of our survey recommended that patients with diabetes receive anti-hypertensive medication(s) if blood pressure consistently equals or exceeds 140 mmHg systolic or 90 mmHg diastolic, with a treatment target of < 130/80 mmHg.[15] This blood pressure target is consistent with recommendations from other expert societies from the United States,[25,26] Australia[13,27,28] and Europe.[16,29-31] Despite this consensus, the current and previous studies[17-22] demonstrate that many patients with diabetes do not achieve this treatment target in clinical practice (Box 2).

Primary and secondary prevention trials provide convincing evidence that lipid lowering reduces the risk of cardiovascular disease and death in people with diabetes.[9] In 2003, the Heart Protection Study group reported that in 5963 patients with diabetes aged 40–80 years with non-fasting total cholesterol levels > 3.5 mmol/L (half of whom had no history of arterial disease at baseline), 40 mg/day of simvastatin significantly reduced coronary mortality and first non-fatal myocardial infarction.[32] The average LDL cholesterol level in diabetic patients treated with simvastatin was ⩽ 2.6 mmol/L. More recently, in a primary prevention study of 2838 participants with type 2 diabetes aged 40–75 years, 10 mg/day of atorvastatin led to a 37% reduction in the incidence of major cardiovascular events.[33] In contrast, the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study recently reported mixed results regarding the effect of fenofibrate on cardiovascular disease events in type 2 diabetes.[34]

Consistent with the findings from these and other studies,[8] the ADA has proposed that statins be commenced for primary prevention in patients with diabetes aged over 40 years if total cholesterol is ⩾ 3.5 mmol/L, with an LDL cholesterol target of < 2.6 mmol/L.[35] Although a similar target was published by the ADA in the year of our audit,[15] our results indicate that only 60% of patients receiving lipid-lowering therapy and 40% of untreated patients had LDL cholesterol levels below this value. These recommendations are consistent with those proposed by other expert groups (Box 3),[13,16,28,29,31,35-38] but conflict with Australian Pharmaceutical Benefits Scheme restrictions for the supply of subsidised drugs, which is probably a significant disincentive for the appropriate use of statins in diabetes management.

In conclusion, our survey of over 600 patients with diabetes indicates that there is significant discord between the evidence-based guideline targets formulated and advocated by physicians, and current treatment outcomes in our own clinical practice. Potential barriers to achieving recommended treatment targets include:[11,39,40]

- reduced patient adherence to prescribed medications because of the number of tablets required to adequately treat vascular risk factors in diabetes, drug interactions and side effects (including hypoglycaemia and weight gain), and inadequate counselling of patients about the benefits and efficacy of primary and secondary prevention of diabetic complications;
- ethnicity and racial factors; and
- prescribing restrictions arising from the reluctance of regulatory pricing bodies to embrace and accept new trial evidence that intensive treatment of cardiovascular risk factors in diabetes significantly reduces the increased morbidity and mortality associated with the disease.

Modification of restrictions by regulatory bodies, the development of medication combinations to reduce polypharmacy, and greater engagement with patients regarding the potential individual benefits and expected adverse effects of medications used to treat glycaemia, blood pressure and lipids may help to modify risk factors in patients with diabetes. However, if resources remain restricted, there may be a need to reassess current treatment recommendations and to prioritise expenditure in order to achieve realistic treatment targets in the increasing number of patients diagnosed with diabetes.

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COMPETING INTERESTS

None declared.

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