Prevalence, care, and outcomes for patients with diet-controlled diabetes in general practice: cross sectional survey

J Hippisley-Cox, M Pringle

Summary

Background Tight glycaemic control reduces microvascular complications in patients with type 1 and type 2 diabetes. We aimed to establish the proportion with type 2 diabetes treated through diet only and to determine levels of complications and quality of care received compared with patients on hypoglycaemic medication.

Methods We undertook a cross-sectional study of 7870 patients with type 2 diabetes from a population of 253 618 patients from 42 general practices in the UK. Our primary outcome was process of care measures and diabetes-related complications.

Findings 31·3% of all patients with type 2 diabetes are being managed with diet only (1% of the total population). More than four-fold variation between practices exists (range 15·6–73·2%). Patients treated with diet only are much less likely to have HbA1c (glycosylated haemoglobin) measurements, blood pressure, cholesterol, smoking, microalbuminuria testing, or screening for foot pulses recorded. 38·4% of patients with type 2 diabetes on medication have a HbA1c, above 7·5% compared with 17·3% of those treated with diet only. Compared with those on medication, patients treated by diet only are more likely to have raised blood pressure and less likely to be on antihypertensive medication; they are 45% more likely to have raised cholesterol and less likely to be prescribed lipid-lowering medication. Although fewer of those treated by diet (68%) have diabetes-related complications compared with those on medication (80%), the rate is much higher than for the population without diabetes.

Interpretation Diabetics treated by diet only have significant rates of complications and are less likely than those on medication to be adequately monitored. There is great scope for improved management within general practice.

Introduction

By tradition, a substantial number of people with diabetes mellitus have been managed without medication. They are usually offered dietary advice and, irrespective of whether patients remember or follow the advice, they are referred to being managed on diet only. Not using medication originated in the era when the aim of treatment was to maintain short-term freedom from symptoms of hyperglycaemia.1 For patients with type 2 diabetes, this meant a stepladder from diet to monotherapy to combined therapy, including the addition of insulin or, more recently, glitazones.2 The use of diet alone was supported by results of early studies that failed to find a convincing association between glycaemic control and the development of complications from diabetes.1 However, the DCCT trial1 published in 1993 provided robust evidence that tight glycaemic control reduces microvascular complications for patients with type 1 diabetes. The UK Prospective Diabetes Study (UKPDS)2–7 subsequently provided strong evidence that good glycaemic control is associated with a reduction of microvascular complications in patients with type 2 diabetes. The UKPDS also showed the need for good blood pressure control in order to help reduce macrovascular complications8,9 and that both interventions are also cost effective.10

The rationale for good glycaemic control in all people with diabetes underpins the National Service Framework for Diabetes,11 the new GP contract12 indicators for the management of diabetes, and NICE guidance on the use of hypoglycaemic drugs.2 Since results of studies show that diet alone does not result in adequate glycaemic control,14 it is likely that many such patients need hypoglycaemic medication.

Translating the results from randomised controlled trials into everyday clinical practice takes time. Anecdotal evidence suggests that there is a continuing belief in the existence of “mild diabetes”—a group of people with diabetes at low risk of complications, for whom active therapeutic management is neither indicated nor cost effective. Since other population-based studies of patients with diabetes have focused on patients on medication14 or on those attending secondary care,15 there are virtually no data from primary care regarding the proportion of patients with diabetes managed on diet only. There is very little information about the level of complications experienced and the quality of care received by such patients.

Therefore, we undertook a large population based study to establish the proportion of patients with type 2 diabetes treated by diet only and the interpractice variation in the use of medication, and to determine levels of complications and quality of care they receive compared with patients on hypoglycaemic medication.

Patients and methods

We undertook a cross-sectional study of 253 618 patients registered on July 15, 2003, across 42 practices in the...
former Trent region. Approval was given by the Trent multi-centre research ethics committee. The coded computerised data in the general practice clinical electronic record were extracted centrally in pseudonymised form by a UK computer software company (EMIS). Although no strong patient identifiers (including the patients’ postcode) were extracted, every patient had been assigned the Townsend score associated with their electoral ward of residence. The Townsend score is a validated measure of material deprivation derived from census related data of the electoral ward associated with the patients’ postcode.16 We validated the resulting database (known as QRESEARCH) by comparing disease prevalence, prescription statistics, population characteristics, referral rates etc, against published data17 and found similar rates per 1000 population. The date of the computer download was July 15, 2003.

We identified patients with diabetes if they had a Read code for diabetes or had more than one prescription for either insulin, sulphonamides, glitazones, biguanides, or for diabetes glucose testing kits.

As in previous studies,18 we classified patients as having type 1 diabetes if they had been diagnosed under the age of 35 years and were receiving insulin. The remaining patients with diabetes were classified as type 2. We then grouped patients with type 2 diabetes into those on medication (defined as one or more scripts for hypoglycaemic agents issued within the last 6 months) and those treated by diet only.

In addition to the patients’ year of birth, sex, diagnosis date, and details of hypoglycaemic agents, we identified individuals with hypertension, ischaemic heart disease, stroke, congestive cardiac failure, atrial fibrillation, or peripheral vascular disease. We grouped patients with any evidence of vascular disease if they had any of the conditions listed above since many had more than one vascular co-morbidity.

We used the Read codes library produced by the UK National Health Service Information Authority19 to identify those with complications related to diabetes. This included amputation or leg ulcer; neuropathy (including impotence); evidence of renal impairment (including dialysis, transplant, nephropathy, or creatinine >120 mmol/L); retinopathy; cataract; or glaucoma (including medication for glaucoma). We grouped patients with either retinopathy, cataract, or glaucoma in to those “with diabetes-related eye disorders”, because many patients had more than one condition.

To measure quality of diabetes care, we identified the most recent value for the following: glycosylated haemoglobin (HbA1c); body-mass index; systolic and diastolic blood pressure; serum cholesterol; and serum creatinine. We defined a raised HbA1c as being above 7.4%; obesity as a body-mass index of more than 30 kg/m²; a raised blood pressure as either a systolic blood pressure higher than 145 mm Hg or a diastolic blood pressure above 85 mm Hg; a raised serum cholesterol as greater than 5 mmol/L and a raised creatinine as a value more than 120 mmol/L. We also retrieved data for retinal screening; testing for presence or absence of peripheral pulses; testing for neuropathy; testing for microalbuminuria; smoking status and smoking cessation advice. All these measures are in the

<table>
<thead>
<tr>
<th>Type 2 diabetes on medication</th>
<th>Type 2 diabetes on diet only</th>
<th>Total number</th>
<th>Adjusted odds ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c recorded ever</td>
<td>4426 (85.6%)</td>
<td>1598 (59.2%)</td>
<td>6568 (76.1%)</td>
<td>0.29 (0.23–0.39)</td>
</tr>
<tr>
<td>Cholesterol recorded ever</td>
<td>4596 (88.5%)</td>
<td>1331 (71.5%)</td>
<td>7066 (81.2%)</td>
<td>0.39 (0.35–0.43)</td>
</tr>
<tr>
<td>Creatinine recorded ever</td>
<td>4727 (92.0%)</td>
<td>2146 (75.5%)</td>
<td>5883 (85.7%)</td>
<td>0.43 (0.38–0.48)</td>
</tr>
<tr>
<td>Blood pressure recorded ever</td>
<td>5192 (96.8%)</td>
<td>2613 (95.6%)</td>
<td>8391 (97.3%)</td>
<td>0.44 (0.34–0.56)</td>
</tr>
<tr>
<td>BMI recorded ever</td>
<td>4879 (94.4%)</td>
<td>2859 (95.3%)</td>
<td>7562 (92.3%)</td>
<td>0.57 (0.47–0.69)</td>
</tr>
<tr>
<td>Smoking recorded ever</td>
<td>5004 (96.8%)</td>
<td>2529 (93.7%)</td>
<td>7573 (94.7%)</td>
<td>0.57 (0.38–0.87)</td>
</tr>
<tr>
<td>Advice on smoking status</td>
<td>399 (6.0%)</td>
<td>129 (4.8%)</td>
<td>525 (7.4%)</td>
<td>0.71 (0.57–0.90)</td>
</tr>
<tr>
<td>Microalbuminuria testing</td>
<td>957 (18.5%)</td>
<td>229 (8.5%)</td>
<td>1252 (15.4%)</td>
<td>0.49 (0.32–0.81)</td>
</tr>
<tr>
<td>Retinal screening recorded ever</td>
<td>506 (98.8%)</td>
<td>189 (7.0%)</td>
<td>744 (8.8%)</td>
<td>0.60 (0.45–0.99)</td>
</tr>
<tr>
<td>Foot pulses recorded ever</td>
<td>2574 (49.8%)</td>
<td>940 (34.8%)</td>
<td>3711 (43.6%)</td>
<td>0.50 (0.30–0.85)</td>
</tr>
<tr>
<td>Neurological testing</td>
<td>36 (0.7%)</td>
<td>3 (0.1%)</td>
<td>40 (0.5%)</td>
<td>0.37 (0.03–5.85)</td>
</tr>
</tbody>
</table>

Table 2: Computer records of clinical care in people with type 2 diabetes
new UK General Medical Services contract for general practitioners.2

We examined the use of anti-hypertensive agents for each patient using categories from the British National Formulary (September, 2003). We identified patients receiving medication within the 6 months before the study period. We also identified patients on monotherapy, dual therapy, and triple or quadruple therapy.

We compared the proportion of patients on lipid-lowering agents and the proportion treated with an angiotensin-converting-enzyme inhibitor. We included these treatments since lipid-lowering treatment has been shown to confer vascular protection in patients with diabetes20 and ACE inhibitors are useful in treating congestive cardiac failure, hypertension, and possibly also confer additional renal protection in patients with diabetes.

Statistical analysis

We used unconditional logistic regression to calculate unadjusted odds ratios with 95% CIs for binary outcomes, comparing patients treated by diet only with those on medication. In our multivariate analysis, we adjusted for sex, age (<40 years; 40–59; 60–79; >80), and fifth of Townsend score (cutoffs were defined using the quintiles for England and Wales). We allowed for clustering by general practice by defining this as a clustered variable; baseline is patients on hypoglycaemic medication.

Role of the sponsor

The funding body had no role in the design of the study, its analysis, in the interpretation of the results, the drafting of the report, or in the decision to submit the paper for publication.

Results

In the study population, there were 8626 patients with diabetes, giving an overall prevalence of 1.4%. Of these, 756 (8.8%) had type 1 diabetes, 5170 (59.9%) had type 2 diabetes treated with medication and 2700 (31.3%) had type 2 diabetes not treated with medication, referred to in this study as “diet only”. The median age at onset was 60 years (IQR 50–68) and 58 years (49–71), respectively. The prevalence of each type of diabetes by sex and quintile of deprivation is shown in table 1. There was more than four-fold variation between the 42 general practices in the percentage of patients with diabetes managed on diet only ranging from 15.6% to 73.2%.

Overall, 76.1% of all patients with type 2 diabetes had ever had an HbA1c measurement recorded on computer; 81.2% had a recorded cholesterol measurement, 85.7% had a creatinine measurement recorded; and more than 92% had smoking, blood pressure, and body-mass index recorded. Although 43.6% of patients had a computer recording for foot pulses, only 14.5% of individuals had microalbuminuria testing recorded, 9% had retinal screening recorded, and 4.9% had testing for neuropathy recorded.

As table 2 shows, patients treated by diet only were significantly less likely than type 2 patients on hypoglycaemic medication to have many measurements recorded, despite adjustments for age, sex, and deprivation, and the general practice they were registered with. For example, patients treated by diet were 71.6% less likely to have an HbA1c recorded compared with those on medication (adjusted OR 0.29, 95% CI 0.21–0.39); 61% less likely to have cholesterol recorded (0.39, 0.28–0.54); 61% less likely to have microalbuminuria testing recorded, 9% had retinal screening recorded, and 4.9% had testing for neuropathy recorded.

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Articles

Patients without diabetes Patients with diabetes Type 2 diabetes on medication Type 2 diabetes on diet only

Any vascular disease 31,687 (13.75%) 1600 (59.3%) 3636 (70.3%) 25215 (10.29%) 1274 (47.2%)
Hypertension 25,215 (10.29%) 2995 (56.2%) 1274 (47.2%)
Ischaemic heart disease 8508 (3.47%) 479 (17.7)
Stroke 4239 (1.73%) 223 (8.3%)
Congestive cardiac failure 2486 (1.05%) 160 (5.9%)
Atrial fibrillation 2674 (1.09%) 178 (6.6%)
Peripheral vascular disease 2621 (1.07%) 131 (4.9%)
Evidence of any diabetes related eye disorders 342 (0.55%) 197 (7.4%)
Retinopathy 12 (0.005%) 948 (18.3%)
Glaucoma 3281 (1.3%) 349 (6.8%)
Cataract 3677 (1.5%) 207 (7.7%)
Bleedness or partially sighted 3191 (0.5%) 62 (2.3%)
Evidence of neuropathy 1330 (1.4%) 254 (9.4%)
Amputation or leg ulcer 1003 (0.4%) 62 (2.3%)
Evidence of renal disease 3159 (1.3%) 495 (9.6%)

*p=245.000. †p=5170. ‡p=2700.

Table 5: Recorded macrovascular and microvascular complications in general population and people with type two diabetes

Table 6: Odds ratio for risk of recorded complication by type of diabetes compared with patients without diabetes

<table>
<thead>
<tr>
<th>Patients without diabetes</th>
<th>Type 2 diabetes on medication vs no diabetes (adjusted odds ratio [95% CI])</th>
<th>Type 2 diabetes on diet only vs no diabetes p value (adjusted odds ratio [95% CI])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any vascular disease</td>
<td>1.0 5.30 (4.64–6.04)</td>
<td>3.75 (2.94–4.77)</td>
</tr>
<tr>
<td>Evidence of diabetes related eye disorders</td>
<td>1.0 5.73 (4.62–7.96)</td>
<td>3.44 (2.46–4.83)</td>
</tr>
<tr>
<td>Evidence of neuropathy</td>
<td>1.0 6.89 (5.70–8.33)</td>
<td>3.46 (2.80–4.20)</td>
</tr>
<tr>
<td>Amputation or leg ulcer</td>
<td>1.0 3.56 (2.07–4.13)</td>
<td>2.01 (2.05–3.11)</td>
</tr>
<tr>
<td>Evidence of renal disease</td>
<td>1.0 2.78 (2.42–3.18)</td>
<td>2.42 (2.05–2.92)</td>
</tr>
</tbody>
</table>

*Odds ratio adjusted for age (20-year age bands), sex, quintile of deprivation, and patients’ general practice (as a clustered variable). †p value is for difference between type 2 diabetes on medication and those on diet alone.

Overall, a significant proportion of patients with type 2 diabetes had a blood pressure above the target threshold of 140/85 mm Hg and this was marginally higher in the diet only group. Of those managed by diet only, 42.9% had a raised blood pressure compared with 41.6% on hypoglycaemic medication (adjusted OR 1·17 95% CI 1·02 to 1·33).

Table 4 shows the usage for each class of anti-hypertensive agent in the subgroup of patients with blood pressure over 140/85 mm Hg. Overall, 32.6% of patients treated by diet only were not on any anti-hypertensive medication compared with 23.7% of those on hypoglycaemic medication (adjusted OR 1·65 95% CI 1·37 to 2·01).

Table 5 shows the percentage of patients with each type of diabetes with evidence of a complication recorded on computer. Overall, of the 5170 on medication, 4137 (80.0%) had at least one complication compared with 1834 (67.9%) of patients managed by diet only. Of the 5170 patients with type 2 diabetes on medication, 70.3% had vascular disease; 29.7% had diabetes-related eye disorders; 16.5% had neuropathy; 9.6% had renal disease and 4.0% had lower limb amputation or leg ulcer.

Table 6 shows the adjusted odds ratio for complications by type of diabetes compared with patients who do not have diabetes, adjusted for sex, age band, deprivation, and general practice. Both patients on medication and those on diet only had substantially increased risk of each complication compared with patients without diabetes. For example, individuals on medication had a much higher risk of vascular disease compared with non-diabetics despite adjustment for age, sex, deprivation, and practice (adjusted OR 5.30, 95% CI 4.64–6.04). For statin prescribed than patients on hypoglycaemic medication (adjusted OR 0·47, 95% CI 0·38–0·59).

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patients treated with diet only, the adjusted odds ratio was 3.75 (95% CI 2.94–4.77).

Patients on medication had a much higher risk of amputation or leg ulcer than the non-diabetic population (adjusted OR 3.56, 95% CI 3.07–4.13). Diet-only patients also had much higher risks (2.01, 95% CI 1.29–3.11). Risks for diabetes-related eye disorders, neuropathy, and renal disease were similarly increased in both patients on medication and those on diet only. Type 2 patients on medication consistently had higher risks than the diet-only patients for each complication except renal disease where the magnitude of the risk was similar (table 6).

Discussion
We found that almost a third of all patients with diabetes are being managed with diet only, that the rate of complications is high, and that routine monitoring in such individuals is much lower than in patients on hypoglycaemic medication. If there were an evidence base showing a balance between side-effects and benefits, or a clear cost-efficiency analysis, this situation might be justified. However, the more than four-fold interpractice variation in the percentage of people with diabetes treated by diet only shows the inconsistency of clinical decision making in this area. This is all the more so since, anecdotally, many people with diabetes on “diet only” do not take their diet seriously. There is clearly considerable scope for improving the care received by these patients.

The overall prevalence of diabetes in our study was slightly higher than that published elsewhere.14,15,21–24 There are several possible explanations; it could reflect the increasing prevalence of diabetes14 and the length of time since other cohorts were identified.15 It could also indicate improved computer recording of clinical data in general practice.25 Another explanation might be that our case definition, which included patients with diabetes on diet only, has not always been possible to implement in other studies of prevalence.14,25 Even a conservative extrapolation from our data could mean that 1% of the total population has diabetes controlled by diet only, which could translate to more than half a million patients in the UK.

Patients with diabetes managed by diet only were less likely to have had almost all of the recommended screening measures recorded, including HbA1c, cholesterol, creatinine, blood pressure, smoking status, and microalbuminuria. They were also less likely to have documented screening for retinopathy or foot pulses. Patients in the diet-only group were less likely to have been referred to a dietitian or chiropodist. They were also less likely to have cholesterol recorded, but when it was recorded it was more likely to be raised and they were less likely to be on statins. Individuals treated by diet only were also more likely to have blood pressure above the target range, and such patients were less likely to be on any antihypertensive medication. The pattern of antihypertensive medication also differed between the two groups, with a greater use of thiazides and a lower use of ACE inhibitors in patients managed by diet only. Since thiazides are relatively contraindicated in diabetes and ACE inhibitors have established positive benefits, individuals treated by diet only are likely to be more at risk of adverse events than those on hypoglycaemic medication.

Our findings might be explained by the fact that these patients are not prompted by the repeat prescribing system to attend for a regular review; the results could also represent a belief among the patients and health professionals that diabetes controlled by diet only is not as serious as that treated with medication. However, our findings suggest that this is not the case. Our most concerning result is the high rate of complications associated with diabetes in those on diet-only treatment. It is true that all complications are more common in the group on medication (80% having at least one diabetes related complication in the medication group compared with 68% in the diet-only group), but the fact that 60% of those treated by diet only have vascular complications, 20% have diabetes-related eye disorders, 9% have neuropathy, and 9% have renal complications is worrying. These rates are all much higher than in the population without diabetes.

The case for more active intervention is undermined by three factors: the fear of inducing symptomatic hypoglycaemia; knowledge of the effects of phenformin, which was withdrawn because of fears of cardiac side-effects and lactic-acidosis;26 and the fact that many people with good glycaemic control still develop complications.1 One in six patients managed by diet only had an HbA1c above the target range. Although this was fewer than the number with raised HbA1c on hypoglycaemic medication, the cross-sectional nature of the data and the lower overall recording rates make interpretation difficult.

Since the Trent region is demographically representative of the UK, the patients registered with practices in the regional research network are known to be representative, in terms of age, gender, deprivation, morbidity, and health service use, of those in Trent.27 We relied on electronic data collection, and were not able to assess the contents of manual records, but have no reason to believe that this would have biased the main comparisons undertaken in our study. Furthermore there is increasing evidence that electronic records are more complete than manual records.28 Since electronic records will be used to monitor implementation of the new UK General Medical Services contract, the methods we have used have reasonable face validity.

The prevalence of complications and cardiovascular risk factors in our study for patients with type 2 diabetes compares well with that reported in clinical trials and studies using patient surveys.29 Other strengths of our study include its size, which is comparable with the total cohort included in UKPDS and that used in other important studies,1,13,14,28 lack of recall bias, and lack of patient recruitment bias. Our data are very recent, and practices, primary care trusts, and policy makers may find
these data useful for benchmarking performance. They will note that overall recording rates for some measures (especially neurological testing and retinal screening) are very low.

Our findings suggest that the management strategy of using diet only in type 2 diabetes is still very common and varies substantially between practices. This suggests inconsistency between clinicians in the decision to introduce hypoglycaemic medication. This result is consistent with other evidence showing variations between practices in clinical areas,27 and is especially important since more patients are cared for solely in general practice than are cared for solely in hospital.28 Patients with diabetes on diet only are receiving less intensive review of their condition, and fewer referrals to, for example, dieticians; they also have a high rate of complications. Although some individuals with type 2 diabetes might be effectively managed by diet only, there is a case for better routine surveillance; for more intensive therapy if glycaemic control, blood pressure, or cholesterol are not optimum, and if any diabetes-related complications occur; and for greater consistency of clinical practice concerning the decision to start medication.

Contributors
J Hippisley-Cox initiated and designed the study, obtained funding and ethical approval, collated the data, undertook data analysis and interpretation, and co-drafted the paper. M Pringle contributed to study design, data interpretation, and co-drafted the paper. J Hippisley-Cox is the guarantor. Both authors had full access to all data in the study, and had final responsibility for the decision to submit for publication.

Conflict of interest statement
MP was co-chair of the External Reference and the Implementation Group for Diabetes National Service Framework (1998–2003). J Hippisley-Cox is the academic director of QRESEARCH—the database used in this investigation.

Acknowledgments
We thank David Stables (EMIS) for undertaking the data extraction, and the general practices who contributed data to QRESEARCH. This study was funded by a grant from the NHS Executive, Trent, UK.

References
1 Nathan D. Some answers, more controversy, from UKPDS. Br J Gen Pract 2003; 53: 837–53.