

Changes in long-term glycemic control and performance indicators in a cohort of type 2 diabetic patients cared for by general practitioners: Findings from the “Modena Diabetes Project”

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Abstract

Background and Aim: General practitioners (GPs) are being increasingly asked to play a key role in the shared care of people with diabetes mellitus, but data concerning the effects of this in Italy are still scarce. We therefore evaluated the 4-year follow-up changes in outcomes and performance indicators in type 2 diabetic patients cared for by GPs in the framework of the “Modena Diabetes Project”.

Methods and Results: Seventy-four percent of the local GPs participating in the project (387 out of 521) sent 5260 paired baseline and follow-up datasheets. The baseline characteristics of the type 2 diabetic patients (49.6% male) were a mean age of 67.3±11.2 years, a mean disease duration of 10.9±7.4 years, a mean BMI of 28.7±4.8 kg/m², and a mean HbA_{1c} level 7.56±1.52%. After four years follow-up, the individual before/after match-paired outcomes revealed an improvement in glycemic control: HbA_{1c} levels significantly decreased to 7.39±1.31%, and the percentage of patients with HbA_{1c} level of <6.5% significantly increased from 15.7% to 22.1%. There was also a significant decrease in body weight (from 78.3±14.8 to 77.6±14.6 kg) and BMI (from 28.8±4.8 to

28.5±4.9 kg/m²). The time trends of glycemic control significantly improved during the 4-year follow up, but those of the body weight and BMI values did not. Furthermore, the percentages of performance indicators matching the expected rate of recurrence per each year of follow-up significantly improved during the study period.

Conclusions: Long-term glycemic control and the performance indicators relating to the type 2 diabetic patients participating in our shared care programme progressively improved. Nutr Metab Cardiovasc Dis (2003) 13: 372–376

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Introduction

Over the last few decades, primary care health professionals have increasingly been asked to play a key role in the shared care of people with diabetes mellitus (1-5).

The Italian Societies of Diabetologists and General Practitioners (GPs) have both published scientific and organisational guidelines concerning the shared care of type 2 diabetes mellitus (T2DM) (6), but the observational data provided by the GPs involved in integrated diabetes care are still limited (7-9).

In 1998, the Modena local health authority designed a shared-care programme in an attempt to direct patients with well-controlled T2DM to the care of their GPs (“Diabetes Project”).

The aim of this study was to evaluate the changes in the

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outcomes and performance indicators in T2DM patients cared for by these GPs during the 4-year period from 1998 to 2002.

Methods

The province of Modena has 630,000 inhabitants, of whom about 16,000 are affected by diabetes. Approximately 6800 (42.5%) of these are cared for by their GPs, including about 1540 disabled patients (*ie* people unable to look after their own bodies and/or incapable of walking by themselves regardless of the cause of their disability). However, as this definition did not allow us to provide relevant information concerning the disabling complications of diabetes (blindness/severe loss of vision, amputation, end-stage renal failure, etc.), we excluded the disabled patients from the analysis, which was therefore restricted to the 5260 datasheets concerning walking patients acquired during the study period.

Our shared-care programme was designed to include only patients with well-controlled T2DM, defined as stable disease with blood glucose (HbA_{1c}) levels of less than 8.0% (a cut-off value agreed by diabetologists and GPs). A "diabetic patient" was defined as an individual with a "fasting blood glucose level of more than 126 mg/dL (>7 mmol/L) on two occasions" or one who had been "previously treated for diabetes".

The quality of care standards to be respected by the GPs were based on the Italian guidelines (6). The performance indicators foresee that every patient should undergo: a) three or more fasting blood glucose measurements per year; b) two or more HbA_{1c} measurements per year; c) one or more dilated eye examinations per year; and d) one or more electrocardiography (ECG) examinations per year. The outcome indicators are: a) the improvement in individual HbA_{1c} levels over time; b) the increase in the percentage of people with HbA_{1c} levels of ≤6.5%; c) the improvement in body weight and BMI over time; and d) the improvement in long-term morbidity and/or mortality. Given that any evaluation of long-term morbidity/mortality requires a follow-up period of at least 10 years, we shall here only describe the results concerning the first three end-points.

Three hundred and eighty-seven of the 521 GPs in Modena agreed to take part in the project, and all the patients enrolled gave their written consent. Although all the patients enrolled must be mainly followed up by their GPs, our protocol foresees the essential role of the team

of diabetes specialists. At the time of disease onset, every newly diagnosed diabetic patient must be referred to them in order to define a tailored medical nutrition therapy and initial drug planning, and to schedule subsequent referrals on the basis of individual disease staging. Furthermore, the patients must also be referred to a specialised diabetic clinic in the case of two consecutive HbA_{1c} measurements of >8.0%, or the occurrence of an acute disease or any non-ordinary event.

The GPs are required to send individual patient baseline and annual follow-up datasheets to the Diabetes Registry kept by the local Health Authority. These datasheets record the patient's age, gender, weight and height; the type of diabetes; disease duration; HbA_{1c} levels; diabetes therapy; the presence of major cardiovascular risk factors [hypertension (resting blood pressure >140/90 mmHg or drug treated), high blood cholesterol levels (fasting value >240 mg/dL or >6 mmol/L or drug treated), high blood triglyceride levels (fasting value >200 mg/dL or >2.2mmol/L or drug treated), and cigarette smoking]; the presence of specialist-certified microvascular (4-stage nephropathy, 4-stage retinopathy, peripheral neuropathy, or diabetic foot) and macrovascular diabetic complications [angina pectoris, myocardial infarction (MI), a transient ischemic attack (TIA)/stroke, chronic heart failure, or *claudicatio intermittens*].

No active HbA_{1c} determinations were performed; the HbA_{1c} values measured in our local laboratories by means of HPLC were reported by the GPs on project datasheets. The cut-off values considered are decided on when the datasheets were designed in 1997 before the project began. However, we have recently included the new cut-off values of the Italian Specialist Societies in our local adaptation of the national guidelines published in 2001 (10), and plan to update our protocol and the datasheets in the next few months.

Descriptive statistics of the baseline and follow-up data were calculated from the Diabetes Registry. The statistical significance of the individual before/after match-paired changes was assessed using Student's *t* test (two-tailed) for the continuous variables and McNemar's chi-squared test (two-tailed) for the percentage variables. Time trends were analysed using a non-parametric test for linear trend that is an extension of Wilcoxon's rank-sum test by Cuzick et al; the formula incorporates a correction for ties. The observation period lasted from January 1998 to December 2002. Significance is expressed by means of 95% confidence intervals (CI) or as a *p* value of *p*<0.05. We used STATA® statistical package for Windows release 7.0.

TABLE 1
Patient characteristics and CV risk factors at baseline
(mean values±SD)

Variable	Values (No. 5260)
Age (years)	67.3±11.2
Sex (male)	49.6%
BMI (kg/m ²)	28.7±4.8
Duration of diabetes (years)	10.9±7.4
Family history of diabetes	51.4%
HbA _{1c} (%)	7.56±1.52
Prevalence of hypertension	59.9%
Prevalence of high blood cholesterol	31.6%
Prevalence of high blood triglyceride	27.6%
Prevalence of cigarette smoking	15.2%

Results

The number of datasheets concerning the T2DM patients cared for by GPs who entered the cohort in the 1st, 2nd, 3rd and 4th years was respectively 180, 1340, 2320 and 1420. The average follow-up was 1.9±0.8 years (range 0.5-4.2).

Table 1 shows the patients' characteristics and the distribution of cardiovascular (CV) risk factors at baseline. The mean age of the population, which was almost evenly divided by gender (49.6 males), was 67.3±11.2 years, disease duration was 10.9±7.4 years, BMI 28.7±4.8 kg/m², and HbA_{1c} 7.56±1.52%.

The match-paired analysis revealed a significant shift

towards less severe stages of microvascular complications. The percentage of patients with micro-albuminuria significantly increased (7.7% vs 12.2%; delta +4.6%, 95% CI: +3.7 to +5.4%), and that of the patients with renal failure decreased (1.7% vs 0.9%; delta -0.8%, 95% CI: -1.0 to -0.4%). There was a significant increase in the number of patients with non-proliferative retinopathy (9.7% vs 10.9%; delta +1.2%, 95% CI: +0.4 to +2.0), and a decrease in the number with proliferative retinopathy (1.3% vs 0.3%; delta -0.3%, 95% CI: -0.5 to -0.03%). The number of patients with peripheral neuropathy significantly increased (6.9% vs 9.5%; delta +2.6%, 95% CI: +1.9 to +3.3). The overall proportion of patients free of cardiovascular diseases decreased from 78.3% to 75.5% (delta -2.8%, 95% CI: -3.6 to -2.0).

There were significant changes in therapeutic patterns (Table 2), with a significant decrease in the number of patients treated with diet alone (31.6% vs 25.3%). There was a significant increase in the patients treated with sulphonylureas alone or combined with biguanides (30.7% vs 33.0%, and 21.8% vs 28.1%), as well as in the number of patients treated with insulin alone or combined with oral hypoglycemic drugs (hypos) (0.5% vs 1.3%), and those receiving new oral hypos plus sulphonylureas or biguanides (0.09% vs 0.16%). No significant change was observed in the percentage of patients treated with metformin alone (4.4% vs 4.7%), whereas the percentage of those on new oral hypos alone significantly decreased (3.4% vs 2.2%).

The individual before/after match-paired outcome data (*ie* glycemic control and body weight) are shown in Table 3. HbA_{1c} levels significantly decreased from 7.56±1.52% to 7.39±1.31%, and the percentage of people with HbA_{1c} lev-

Diabetes therapy	Before (%)	After (%)	Delta change (95% CI) in matched pairs
Diet alone (%)	31.6	25.3	-6.3 (from -7.2 to -5.5)
Sulphonylureas (%)	30.7	33.0	+2.3 (from +1.1 to +3.4)
Sulphonylureas plus biguanides (%)	21.8	28.1	+6.3 (from +5.4 to +7.2)
Metformin (%)	4.4	4.7	+0.3 (from -0.3 to +0.8)
Insulin (%)	0.2	0.3	+0.1 (from +0.05 to +0.3)
Insulin plus oral hypoglycemic drugs (%)	0.3	1.0	+0.7 (from +0.02 to +0.7)
New oral hypoglycemic drugs alone (%)	3.4	2.2	-1.1 (from -1.6 to -0.7)
Sulphonylureas plus new oral hypos (%)	0.03	0.06	+0.03 (from +0.01 to +0.05)
Biguanides plus new oral hypos (%)	0.06	0.1	+0.01 (from +0.001 to +0.02)

Average follow-up 1.9±0.8 years (range: 0.5-4.2 years)

TABLE 2
Therapeutic pattern and long-term individual match-paired changes
(No. 5260)

Variable	Before	After	Delta change (95% CI) in matched pairs
HbA _{1c} (%)	7.56±1.52	7.39±1.31	-0.16 (from -0.20 to -0.12)
Percentage of patients with HbA _{1c} ≤6.5%	15.7%	22.1%	+6.4 (from +5.4 to +7.4)
Body weight (kg)	78.3±14.8	77.6±14.6	-0.75 (from -0.87 to -0.62)
BMI (kg/m ²)	28.8±4.8	28.5±4.9	-0.34 (from -0.40 to -0.28)

Average follow-up 1.9±0.8 years (range: 0.5-4.2 years)

TABLE 3

Long-term individual match-paired changes in glycemic control and body weight (mean values ± SD; No. 5260)

els of ≤6.5% significantly increased from 15.7% to 22.1%. Body weight significantly decreased from 78.3±14.8 to 77.6±14.6 kg, and BMI from 28.8±4.8 to 28.5±4.9 kg/m².

The follow-up trends concerning outcome and performance indicators are shown in Table 4. Both the mean HbA_{1c} value and the percentage of people with HbA_{1c} levels of ≤6.5% significantly improved over time, whereas the body weight and BMI values did not. With regard to the performance indicators, the percentage of practices adhering to the protocol changed from 64% to 85% in terms of the number of blood glucose measurements/year, from 74% to 95% in terms of the number of HbA_{1c} measurements/year, from 62% to 88% in terms of the number of dilated eye examinations/year, and from 65% to 90% in terms of the number of ECG examinations/year.

Discussion

Diabetes mellitus is a major and still growing health problem (11), and organising the care of affected patients has become an important public health issue. The relationship between primary and secondary care is the key aspect of many health care programmes worldwide, and there is a typical disease management model (12).

Our study has a number of limitations because we did not use a random sample, and the lack of a control group means that the observed before/after changes may have been due to reasons other than those considered by the project itself. Nevertheless, we believe that our data can provide some interesting information concerning the long-term monitoring of the shared-care of patients with T2DM.

TABLE 4
Trends of outcome and performance indicators during the project

	Project start No. 180* (mean±SD)	1 st year No. 1340* (mean±SD)	2 nd year No. 2320* (mean±SD)	3 rd year No. 3840* (mean±SD)	4 th year No. 5260* (mean±SD)	Significance of trend <i>p</i>
Outcome indicators						
HbA _{1c} (%)	7.56±1.52	7.52±1.38	7.51±1.36	7.33±1.28	7.28±1.28	<0.01
Percentage of patients with HbA _{1c} of ≤6.5%	15.7%	23.4%	22.8%	27.3%	29.1%	<0.01
Body weight (kg)	78.3±14.8	77.1±14.9	76.2±14.7	76.6±14.6	77.9±14.7	ns
BMI (kg/m ²)	28.8±4.8	28.6±4.8	28.2±4.8	28.3±5.0	28.6±5.1	ns
Performance indicators						
No. of blood glucose measurements (≥3 per year)	n.a.	64%	80%	84%	85%	<0.01
No. of HbA _{1c} measurements (≥2 per year)	n.a.	74%	83%	91%	95%	<0.01
No. of dilated eye examinations (≥1 per year)	n.a.	62%	71%	81%	88%	<0.01
No. of ECGs (≥1 per year)	n.a.	65%	77%	85%	90%	<0.01

n.a. = not available because the baseline datasheet did not contain the item

* Number of individual datasheets evaluated each year: newly enrolled patients plus those enrolled in the cohort in previous years (cumulative data per year).

We found that the well-controlled T2DM patients cared for by GPs and adhering to the shared-care programme were elderly and overweight. They also had a high prevalence of other CV risk factors, with about two-thirds being hypertensive and/or dyslipidemic (Table 1).

The therapeutic patterns were mainly oriented towards the use of sulphonylureas alone (which increased from 31% to 33%) or combined with biguanides (which increased from 22% to 28%). The use of metformin alone remained low throughout the observation period (4.4% at baseline and 4.7% at the end of the follow-up). The baseline body weight of our patients was unexpected (Table 2).

The individual match-paired outcomes at the end of the follow-up showed improvements in both glycemic control and body weight (Table 3).

The time-trends of glycemic control significantly improved regardless of body weight, as did the percentages of the performance indicators matching the expected rate of recurrence per each year of follow-up (Table 4).

The next step will be to assess the long-term changes in morbidity and/or mortality, which was not considered in this study because we believe that the related follow-up period should be at least 10 years.

In conclusion, although our findings may be limited by the lack of a control group, long-term glycemic control and performance indicators progressively improved among the T2DM patients involved in our shared-care programme.

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