Changes in diabetes care introduced by a Chronic Care Model-based programme in Tuscany: a 4-year cohort study

Francesco Profili¹, Irene Bellini², Alfredo Zuppiroli¹, Giuseppe Seghieri¹, Fabio Barbone³,⁴, Paolo Francesconi¹

¹ Regional Health Agency of Tuscany, Florence, Italy
² Medical Specialisation School of Hygiene and Preventive Medicine, Florence, Italy
³ Department of Medical Sciences, University of Trieste, Trieste, Italy
⁴ Department of Medical and Biological Sciences, University of Udine, Udine, Italy

Correspondence: Francesco Profili, Regional Health Agency of Tuscany, via Pietro Dazzi 1, 50141 Firenze, Italy, Tel: +3933357757645; e-mail: francesco.profili@ars.toscana.it

Introduction

Tuscany is an Italian region with ~3.7 million inhabitants, with a proportion of old and very old people among the highest in the world, and further increasing. Age-related chronic diseases are therefore very frequent.¹

Among chronic diseases, diabetes, a non-communicable disease with a significant impact on the quality of life, health services and costs, is the main cause of morbidity because of its complications.²

In 2013, there were 205,000 diabetics in Tuscany among the population aged >15 years, with a prevalence of 6.4%, with an increasing trend during the last 10 years.³

For the management of chronic diseases, interventions based on Chronic Care Model (CCM) have been widely applied in other countries, such as USA and Northern European countries, and many studies regarding its effectiveness have been published.⁴-⁹ Most of them reported an improvement in care quality¹⁰-¹³ and an increased adherence to the standard guidelines¹¹-¹⁴ for diabetes, showing a better control of glycated haemoglobin (HbA1c), blood pressure and cholesterol levels.¹¹-²¹ Other studies evidenced reduced accesses of less urgent cases to emergency departments, a decreased hospitalisation rate, a lower heart disease risk and a higher survival time among patients enrolled.²²-²⁵

Tuscany has been applying a CCM-based programme since 2008 (described in more detail below) aimed at better care of chronic patients, among whom diabetic patients are included. It was similar to the experience of patient’s centered medical home (PCMH), where home-dwelling chronic patients are taken in charge by an integrated team with a proactive approach, focused on the improvement of life quality and on the prevention of complications.²⁶-²⁸ The objective of this study was to evaluate the impact on the care of type 2 diabetic patients after 4 years from the start of the CCM-based programme, considering both process (laboratory tests and specialist visits) and outcome indicators (hospitalisation and survival rate).

Methods

Study design

Population-based cohort study, which includes patients with type 2 diabetes (from now on simply diabetes), aged over 15 years, living in Tuscany. Follow-up period went from 1 January 2011 to 12 December 2014.

Settings

Italy has a tax-based universal health system organised on three levels. The national level has a funding role and dictates the fundamental services, yearly updated, that must be provided to every inhabitant, called LEA (essential levels of assistance). The regional level receives the national funding and organises the health systems autonomously through a network of Local Health Authorities (LHAs). Every inhabitant is entitled to choose a GP, who has a gatekeeper function and a maximum of 1500 patients in charge. Co-payments of some health services might be requested. LHAs are further divided into different health districts, homogeneous for...
some characteristics (e.g. rural vs. urban vs. mountain areas), where primary care is organised.

In 2008, the Tuscan Regional Health Ministry launched the ‘Project for proactive health care implementation at community level’,\textsuperscript{29} based on the CCM\textsuperscript{30,31} for the management of four chronic diseases: type 2 diabetes, chronic stroke, heart failure and chronic obstructive pulmonary disease. CCM-based programme started on 6 January 2010 with a pilot group (483 GPs out of 2700). Other GPs joined after 2010 reaching 60% in 2014. GP adherence was voluntary throughout all CCM-based programme implementation period.

**Population**

According to an algorithm based on administrative data from the regional health database,\textsuperscript{32} patients were considered affected by diabetes in case of any of the following criteria: oral antidiabetics or insulin assumption twice during the preceding year, hospital discharge with primary or secondary diagnosis of diabetes, and/or co-payment exemption due to a diabetes diagnosis.

All patients selected for the study met the following inclusion criteria:

- met the diabetes case definition on 1 January 2006 (in order to have a reference to the previous period of disease care);
- were still alive on 4 January 2011 (in order to reduce a source of selection bias due to the possibility that patients with a higher short-term death risk were not enrolled in CCM-based programme);
- had not been changing GP or LHA of residence since 2006 (in order to reduce exposure misclassification).

All patients assisted by GPs who joined the CCM-based programme after 2010 were excluded because the lists of enrolled patients were not available.

Three LHAs out of 12 did not send lists of enrolled patients, so analyses were restricted to the remaining 9 LHAs, with 2 578 902 inhabitants older than 15 years, corresponding to 79% of the Tuscan population.

**Data sources**

Administrative data from the regional health database were used: hospital discharges, drug prescriptions, diagnostic procedures and referral visits, disease-specific exemptions from co-payment to health care, mortality and registry office database.

LHAs regularly updated the list of the GPs adhering to the CCM-based programme and sent the list of patients enrolled during the first 2 months (April–May 2010) to consent to monitoring at regional level.

Patients have a unique personal identification code anonymised, according to the privacy law, but allowing record-linkage to be carried out between administrative data and LHAs enrolled lists.

**Measures**

Enrolment in CCM-based programme is the exposure variable. The presence of patients in the lists of enrolled patients identifies exposure status.

Linking cohort patients with CCM-enrolled patients resulting from LHA reports we defined our exposure groups as follows (patients in enrolled lists are all assisted by GPs that joined the CCM-based programme):

- notCCM, diabetic patients assisted by GPs that never joined the CCM-based programme;
- enrolled CCM, patients linked with enrolled lists of GPs that joined the CCM-based programme;
- not enrolled CCM, patients assisted by GPs who joined the CCM-based programme, but not linked with enrolled lists (observed only in preliminary analysis to evaluate selection bias and then excluded).

The CCM-based programme involves a shifting from a reactive to a proactive approach, focusing on the maintenance of health with multi-professional interventions, characterised by: multi-professional teams that manage the patient, active role of patients and health education programmes, personalised evidence-based therapeutic plan for each patient, scheduled follow-up, shared clinical information, implementation of primary prevention.

The adherence of GPs to the project was voluntary. GPs chose patients to be enrolled in the project and asked them for their informed consent. Consequently, not every patient assisted by a GP that joined the CCM-based programme was enrolled.

The pivotal unit of the implementation was a specific clinical team, including from 5 to up to 15 GPs, a nurse and a health worker. Each team had ~10 000 patients.

The activity was carried out in the main practice. Health professionals had to adopt a predefined follow-up protocol for each disease. Diabetes patients were periodically monitored for: blood pressure, waist circumference, HbA1c, cholesterol, electrolytes, urine, blood glucose and microalbuminuria, BMI, lifestyle, eating habits and adherence to the therapy, foot, cardiovascular, ocular and neurological complications. Desired parameters were personalised in order to assure monitoring of diabetes, and prevent its evolution.

The nurse was responsible for data updates, contacting and helping patients for routine services, and carrying out the detection of clinical parameters. Team activities were supported by the appropriate use of electronic health records.

As outcomes, the study measured:

- The Guideline Composite Indicator (GCI), which is a proxy of fair adherence to follow-up guidelines,\textsuperscript{33} included an annual assessment of glycated haemoglobin and at least two assessments among eye examinations, total serum cholesterol and microalbuminuria. The GCI indicator was estimated as the number of years in which a patient has done assessment of glycated haemoglobin and at least two assessments among eye examinations, total serum cholesterol and microalbuminuria on total person-years.
- General Hospitalisations rate.
- Hospitalisations rate for:
  - uncontrolled diabetes;
  - short-term diabetes complications (ketoacidosis, hyperosmolarity, coma, hypoglycaemia);\textsuperscript{34}
  - long-term diabetes complications: cardiovascular complications (hypertension, ischemic and other heart disease, atherosclerosis, aneurysms, embolism, thrombosis, hypotension, ulcers, chest pain);
  - neurological complications (peripheral autonomic neuropathy, disorders of the peripheral nervous system, cerebrovascular disease, diabetic arthropathy, radiculopathy, diabetic bone diseases);
  - ophthalmic complications (disorders of the eye, adnexa);
  - renal diseases (nephritis, nephritic syndrome, nephrosis, diseases of urinary system, proteinuria, albuminuria);
  - endocrine metabolic effects (endocrine, metabolic and immunity disorders);
  - amputations of lower extremities;
  - acute cardio-cerebrovascular complications (stroke, ST segment elevation myocardial infarction).

All ordinary admissions, excluding long-term care and rehabilitation setting, were considered for hospitalisation rates. Specific primary diagnoses and surgery procedure codes selected to define diabetes complications are shown in Table A of Supplementary Data. All long-term complications subgroups are mutually exclusive, except acute cardio-cerebrovascular group that contains specific diagnoses: ST segment elevation myocardial infarction from cardiovascular and stroke from neurological complications.

- All causes mortality rate.

Other variables measured were: age (at 1 January 2011), gender, LHA of residence, number of different therapeutic/pharmacological
subgroups drugs level 3 Anatomical Therapeutic Chemical (ATC3) classification taken during last year, all chronic diseases detectable from administrative data (chronic heart failure, previous stroke, dementia, chronic obstructive pulmonary disease – COPD, chronic ischemic heart disease, hypertension).

Statistical analyses

Descriptive analyses and Pearson’s chi square tests were performed to evaluate differences between patients at baseline (enrolment period) for possible confounding factors, then exposed (enrolled CCM patients) and unexposed (not-CCM patients) groups were matched using a propensity score approach (logit model, 1:1 nearest neighbour matching, caliper: 0.02). Age, gender, LHA of residence, number of different ATC3 taken during the preceding year and other chronic diseases at baseline were included in the propensity score because a priori confounders, confirmed by preliminary analyses.

Crude incidence rates (IR) and incidence rate ratio (IRR), for hospitalisation and GCI outcomes, were estimated for the preceding period (2006–9). Crude mortality rates and incidence rates for hospitalisation and GCI outcomes were, by contrast, estimated in the follow-up period.

After matching a conditional (on matching pairs) fixed effect Poisson regression model (robust standard errors) was performed to estimate IRR for hospitalisation and GCI outcomes, adjusting for individual outcome values measured previously (2006–9). The Poisson regression model was chosen to model count data and take into account person years of observation. Hazard ratio (HR) of mortality was estimated using stratified Cox regression (robust standard errors).

Finally, stratified analyses for type of admission (planned or urgent) were also implemented for hospitalisation outcomes whenever possible. Short-term complications, uncontrolled diabetes and acute cardio-cerebrovascular complications were excluded from stratified analyses because they were, by definition, urgent hospitalisations.

All analyses were performed using STATA 12.

Results

Overall, 61 293 prevalent diabetes patients on 1 January 2006, living in one of nine Tuscan LHAs in study, being alive at 4 January 2011, who never changed GP or LHA after 2006, were identified.

GPs who joined the CCM-based programme assisted 14 016 diabetes patients, among which 8574 (61.2%) were enrolled (enrolled CCM group or exposed), and 5442 were not (not-enrolled CCM group). About 47 277 patients were assisted by a GP who did not join CCM-based programme (not-CCM group or not exposed).

Considering firstly the comparability of these three groups, significant differences were found regarding age, gender, comorbidities and drug prescriptions (table 1). There were also geographical differences (LHA of residence) due to different CCM-based programme diffusion level in each LHA (data not shown). Death risk during the follow-up period, adjusted for age, was 5.6% (95% CI 5.5–5.7%) in the not-CCM group, and 5.8% (95% CI 5.4–6.1%) in the not-enrolled CCM group.

After propensity score matching was conducted and not exposed in order to be able to compare groups, data were restricted to 8486 patients in each group, accounting for 99% of the original CCM group and 18% of original not-CCM group (table 1).

Matched groups showed some differences in GCI value and hospitalisations for diabetes complications during the 2006–9 period (table 2).

Results in follow-up period analysis revealed an important increase of GCI in exposed (46.2%) compared with not exposed (28.8%), resulting in an IRR of 1.58 (95% CI 1.53–1.62, P < 0.001).

Exposure to CCM-based programme did not modify all causes hospitalisation (table 3), incidence rates were nearly 273 per 1000 person years in both groups. Type of admission (planned or urgent) did not significantly change either, but a trend toward the increase in planned hospitalisations was observable (table 4). A significant reduction was observed only in urgent hospitalisation for neurological long-term complications, IRR of 0.80 (95% CI 0.69–0.94).

Focusing on the long-term causes, hospitalisations for cardiovascular long-term complications increased with an IRR of 1.11 (95% CI 1.04–1.18).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Not CCM/not exposed</th>
<th>CCM Enrolled/exposed</th>
<th>CCM not enrolled</th>
<th>Total</th>
<th>Matched 1:1 groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=47 277</td>
<td>n=8574</td>
<td>n=5442</td>
<td>n=61 293</td>
<td>n=8486</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>5.3</td>
<td>2.6</td>
<td>9.0</td>
<td>5.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>50–59</td>
<td>10.5</td>
<td>10.0</td>
<td>11.5</td>
<td>10.5</td>
<td>9.9</td>
</tr>
<tr>
<td>60–69</td>
<td>24.6</td>
<td>27.3</td>
<td>21.2</td>
<td>24.6</td>
<td>27.4</td>
</tr>
<tr>
<td>70–79</td>
<td>34.2</td>
<td>38.3</td>
<td>28.8</td>
<td>34.3</td>
<td>38.5</td>
</tr>
<tr>
<td>80+</td>
<td>25.4</td>
<td>21.9</td>
<td>29.5</td>
<td>25.3</td>
<td>21.6</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49.6</td>
<td>51.5</td>
<td>45.7</td>
<td>49.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>50.4</td>
<td>48.5</td>
<td>54.3</td>
<td>50.5</td>
<td>48.6</td>
</tr>
<tr>
<td>Number of different ATC3 drug codes taken during last year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4</td>
<td>19.8</td>
<td>16.2</td>
<td>28.3</td>
<td>20.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4–6</td>
<td>28.1</td>
<td>31.0</td>
<td>26.9</td>
<td>28.4</td>
<td>31.2</td>
</tr>
<tr>
<td>7–9</td>
<td>26.4</td>
<td>27.5</td>
<td>21.3</td>
<td>26.1</td>
<td>27.4</td>
</tr>
<tr>
<td>10+</td>
<td>25.7</td>
<td>25.3</td>
<td>23.5</td>
<td>25.5</td>
<td>25.2</td>
</tr>
<tr>
<td>Prevalence of other chronic diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>11.9</td>
<td>10.9</td>
<td>12.3</td>
<td>11.8</td>
<td>0.007</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>5.8</td>
<td>4.8</td>
<td>6.6</td>
<td>5.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cardiopathy</td>
<td>9.9</td>
<td>9.9</td>
<td>9.9</td>
<td>9.9</td>
<td>0.994</td>
</tr>
<tr>
<td>Hypertension</td>
<td>78.9</td>
<td>80.7</td>
<td>74.7</td>
<td>78.8</td>
<td>0.001</td>
</tr>
<tr>
<td>Dementia</td>
<td>3.0</td>
<td>1.9</td>
<td>4.2</td>
<td>2.9</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

a: Pearson’s chi square P value.

Table 1 Baseline matching characteristics of patients, before and after propensity score matching.
Instead, protective effects for neurological long-term complications risk, IRR of 0.85 (95% CI 0.76–0.95), and for acute cardio-cerebrovascular long-term complications (stroke and ST segment elevation myocardial infarction), IRR of 0.81 (95% CI 0.71–0.92), were observed.

A reduction in mortality during the follow-up period (starting from 4 January 2011) was registered in the CCM group (mortality rate 4.2%) compared to the not-CCM group (4.6%). The HR between CCM and not-CCM matched groups was 0.88 (95% CI 0.81–0.96, P = 0.003).

**Discussion**

In Tuscany, implementing the CCM-based programme produced significant impacts on the care of patients with diabetes. Enrolled patients were much more likely to be followed up according to clinical recommendations, all diagnoses hospitalisation rates did not change significantly, though there was an increase in hospitalisation due to chronic cardiovascular complications and a decrease in neurological and acute cardio-cerebrovascular complications. There was an almost significant increase in planned but not in urgent hospitalisation for total long-term complications, a decrease in neurological complications was observed only for urgent admissions while, on the contrary, the increase in chronic cardiovascular complications was more pronounced and significant for planned admissions. Mortality decreased significantly.

The increase in GCI value confirmed the efficacy of the more proactive approach of the CCM-based programme. This result is coherent with other studies on CCM-based programmes conducted both in USA and Europe. Considering GCI as a proxy of adherence to guidelines, we can assume that a patient enrolled in a CCM-based programme has a probability of 58% higher to be treated according to the guidelines.

The interpretation of results pertaining to hospitalisation is more complex. The lack of expected changes in hospitalisation rates for all causes is coherent with some studies on hospitalisation in diabetes patients conducted in PCMH, but differs from the findings of other studies, which detected a reduction in hospitalisation or emergency department accesses. Other experiences of primary care intervention, indeed, showed an increased hospitalisation risk for disease-related diagnoses. Comparability with other studies can be limited by use of different diagnosis criteria and admission type.

The higher risk of admission for cardiovascular long-term complications observed could be due to an initial screening effect of the CCM-based programme. Indeed, an increase in diagnoses of complications in patients with diabetes, undetected in the past, may have been determined through a proactive behaviour by general practitioners who adhered to the CCM-based programme which may have induced additional physical examinations, laboratory analyses, a general greater attention to patient conditions, and consequently a higher hospitalisation rate for cardiovascular long-term complications.
complications. What we have found, however, was that this increased admission rate for cardiovascular diseases (ischemic heart disease, heart failure, hypertension) was accompanied by a significant decrease in acute cardio-cerebrovascular long-term diseases. CCM-based programme patients showed, indeed, a reduced risk of stroke and ST segment elevation myocardial infarction. This could be, in our opinion, linked with a greater attention by GPs, who improved their awareness of patients’ clinical conditions which subsequently resulted into a greater hospitalisation rate. This was also suggested by the observation that there was an almost significant increase in planned but not in urgent hospitalisation for total long-term complications, and that the increase in chronic cardiovascular complications was more pronounced and significant for planned than for urgent admissions. In addition, the reduced risk of stroke could be due to the fact that prevention of acute cardio-cerebrovascular disease requires a multifaceted clinical attention to several risk factors (i.e. hypertension, atrial fibrillation and heart failure) which may be cumulatively better addressed by GPs with a more proactive aptitude.

This hypothesis finds moreover a plausible explanation in a sort of ‘paradox’ since our data indicate that, even if hospitalisations for cardiovascular long-term complications significantly rise across the follow-up period, results of survival analysis show a significant reduction in mortality rates among the CCM-enrolled patients, consistent with reduction in stroke and myocardial infarction rates. Other studies showed similar results with different follow-up periods,29,30 showing the beneficial effects on health status by a proactive action of GPs.

In other words, these results suggest that hospitalisation cannot be regarded as a systematically negative outcome. It was likely that some hospital admissions were life-saving, improving the probability of survival by a reduction of more catastrophic events. In addition, the differences between planned and urgent admission, although not statistically significant, suggest a trend toward the increase in controlled and planned hospitalisations, and thus suggesting that such admissions could have been agreed by GPs with hospital specialists.

Propensity score matching and adjustment of each indicator for individual outcome of the previous period was implemented to reduce potential selection bias and place groups at a comparable level, but the exclusive use of administrative data and the lack of clinic information regarding the real health status of patients could represent a limit. Residual uncontrolled bias could be detected through a direct observation of medical records.

Even if with the limitation of a retrospective observational design, the main strength of the study was consistent with the availability of a large database from a region with a homogeneous primary care delivery system, allowing researchers to follow up with sufficient affordability robust outcomes such as mortality or reduced risk of acute cardiovascular events from a real world’s scenario.

Conclusions

The implementation of a regional CCM-based programme for patients with diabetes was followed by a greater adherence to guidelines, a lower risk of acute cardio-cerebrovascular events and by improved survival. This positive scenario for health status of patients could engender cost-efficacy issues in the future, also due to the observed increase in hospitalisations for cardiovascular long-term complications. Certainly, cost-effectiveness studies should be implemented. It is likely that more positive effects on hospitalisations and cost savings will be observed as soon as the described screening effect is reduced. In the same way, better integrated care (GPs and specialists) of patients at community level and more appropriate specialist outpatient services organisation could reduce a part of observed hospitalisation, maintaining the benefits seen for acute cardio-cerebrovascular events and survival.

Limitations and strengths of the study

Study limitation may depend on the comparability of enrolled and not-enrolled patients. Firstly, descriptive analyses showed a plausible selection bias due to an opportunistic enrolment of patients by GPs during the first 2 months. Probably GP-enrolled patients visited more frequently, excluding highly compromised patients with more chronic diseases and older than 80 years. Besides, groups showed significant differences in outcomes already before 2010. Secondly, these differences could also depend on unobservable characteristics of GPs and different attitudes in treatment compliance of patients.

Limitations and strengths of the study

Study limitation may depend on the comparability of enrolled and not-enrolled patients. Firstly, descriptive analyses showed a plausible selection bias due to an opportunistic enrolment of patients by GPs during the first 2 months. Probably GP-enrolled patients visited more frequently, excluding highly compromised patients with more chronic diseases and older than 80 years. Besides, groups showed significant differences in outcomes already before 2010. Secondly, these differences could also depend on unobservable characteristics of GPs and different attitudes in treatment compliance of patients.

Key points

- The evaluation of the CCM for diabetes management in Tuscany revealed:
- an improvement in adherence to diabetes guidelines;
- a decrease of hospitalisation for acute cardio-cerebrovascular hospitalisation (stroke and ST segment elevation myocardial infarction) and an improved survival.

Funding

The authors belong to the Regional Health Agency of Tuscany, funded by Regional Health Authority of Tuscany. One author, belonging to the University of Trieste (Italy), has collaborated as advisor.
Supplementary data

Supplementary data are available at EURPUB online.

Conflicts of interest: None declared.

References

29. AIRT 2012. Accordio Regionale ai sensi dell'artt. 4, 14 e 1bis dell’Accordo collettivo nazionale per la disciplina dei rapporti con i medici di medicina generale 29.07.09.