Improving the quality of care in patients with Type 2 Diabetes Mellitus: an audit study in a general practice setting

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Type 2 Diabetes Mellitus (T2DM) is fast evolving as one of the world's largest human health issue. The 80% of patients with T2DM are managed by Primary Care Physicians (PCPs), but its respective quality of care is still unsatisfactory. Thus, effective strategies to improve diabetes treatment in general practice are urgently needed. The aim of this study was to test the effect of an internal and external cycle-audit study in improving the quality of care of T2DM by using an ad hoc software. Our sample included 196 Italian Primary Care Physicians (PCPs) trained to enrol at least 25 patients with T2DM from July, 1, 2006 to March, 1, 2007. The definition of "quality of care" was based on a series of pre-specified performance measures. They were applied in the 5-cycle-three-monthly internal audit, where each PCP assessed his own performance, and 3-cycle-once-yearly external audit, where all patients' records were reviewed and discussed by a local panel of PCPs and diabetologists. Overall, 4507 patients affected by T2DM were enrolled. HbA_{1c} monitoring was 30% significantly higher between the first and the last audit phase, and the LDL-C checking increased more than 50% during follow-up. Furthermore, there was an almost 50% reduction of patients with $HbA_{1c} \geq 53$ (ie, 7%) and 75 mmol/mol (ie, 9%), as well as a significant decrease for those outside target for LDL-C cholesterol and BMI. Although there was a significant improvement in the proportions of patients achieving BP goals, the use of antihypertensives were not increased after the third audit phase. Cycles audit significantly improved several indicators of the T2DM management. They also increased glucose, cholesterol and some aspect of blood pressure control. Investments aimed to enhance the shared management between PCPs and specialists are likely to further ameliorate the management of patients with T2DM.

Introduction

Type 2 Diabetes Mellitus (T2DM) is fast evolving as one of the world's largest human health issue. Its growing prevalence is now being strongly associated with a longer life expectancy, a more sedentary lifestyle and a greater tendency towards obesity [1]. The disease is mainly diagnosed in adults over 40 years of age, although increasingly, it is being found to have developed in younger people, including children [2]. The CODE-2 study, conducted in eight European countries, have estimated an average cost for a patient with T2DM of 2,834 € per year. The highest costs (~60%) were attributed to hospitalizations due to the long-term complications of diabetes, whereas drug consumption ranged 13-29% of the total costs [3].

In this context, a careful monitoring of Patients with T2DM, which mainly consists in reaching evidence-based goals for Haemoglobin A_{1c} (HbA_{1c}), systolic and diastolic Blood Pressure (BP), and Low-Density Lipoprotein (LDL) cholesterol levels, seems to sensibly decrease both micro (ie, retinopathy, nephropathy and neuropathy) and macro-vascular (ie, coronary and cerebrovascular) diabetes complications, so reducing the related healthcare costs [1,4].

In western countries the majority of patients with T2DM are predominantly managed by Primary Care Physicians (PCPs) and diabetologists. Even though the T2DM care seems unsatisfactory in both of these settings, more than 80% of diabetes long-term treatments is delivered by PCPs. Thus, effective strategies to improve diabetes care in GP are urgently needed [5,6].

Recently, the widespread use of software systems for managing patients' information among PCPs, has dramatically increased the availability of electronic records. Such information can be programmed to include sophisticated clinical algorithms with which to measure quality of care (ie, performance measures), so making possible to identify clinical issues and to take actions for addressing them [7].

Although it seems relatively easy to improve performance for simple processes of care, the amelioration of important intermediate outcomes such as HbA_{1c}, BP, and LDL cholesterol does not seem straightforward [8,9]. Some care systems with intense disease management programs have improved processes of care, but not necessarily intermediate outcomes, mostly because of medication non-adherence [8,10,11].

Two Australian studies [12,13] retrieved an encouraging improvement in the screening of Patients with T2DM, but most of the hypertensive and displidemic enrolees were still outside target because pharmacologically undertreated. Furthermore, prior investigations were mostly performed outside Europe, and they often excluded lifestyles aspects (ie, body mass index – BMI –, smoking habits), as well as appropriate use of drugs.

We developed the "Diabetes and Evaluation of Care: Observational Research (DECOR)", a cycle audit process through a panel of Italian PCPs, aimed to evaluate the possible improvements in quality of care among patients with T2DM. The definition of "quality of care" was based on a series of "process" and "intermediate outcome" measures, and a dedicated electronic template was purposely implemented in the PCP's standard software.

Methods

Study population

One-hundred-ninety-six PCPs, homogenously distributed across Italy, were trained to enrol at least 25 patients aged ≥ 18 years, diagnosed with T2DM (ICD9CM codes: 250.xx, excluded 250.x1 and 250.x3) and actively included into their list from July, 1, 2006 to March, 1, 2007. The date of T2DM diagnosis (index diagnosis) was also adopted to define participants' features at the baseline.

Patients included in the study cohort have to be registered with one of the participating PCPs for at least 1 year before entry into the study and survived at least 18 months after the index diagnosis. They were excluded as suffering from type I or gestational diabetes, kidney failure (creatinine > 2.5 mg/dL) and/or dialysis, blindness, retinopathy, macular oedema, ketoacidosis, severe heart failure [14,15], being permanently in-bed, and having severe co-morbidities which could impede the usual care.

Performance measures

On the basis of a series of consensus meetings, a panel of PCPs and diabetes specialists revised the official guidelines concerning the prevention and treatment of T2DM [10,16,17] and evaluated the applicability of the pre-selected measures into the DECOR template. This software allows to collect demographic details that are linked through the use of an encrypted patient code with medical records (diagnoses, tests and tests results), drug prescription information (medication name, date of filled prescriptions, and number of days' supply), hospital admission, and date of death.

Table I depicts the final list of twelve "process" and eleven "intermediate outcome" measures being selected at the end of the consensus process.

As recommended by the best clinical practice [10,16,17], biological parameters such as HbA_{1c}, BP, and LDL cholesterol levels, were constantly under monitoring and re-evaluation; lifestyle changes were focused on BMI and smoking habit. Cardiovascular (ie, echocardiography) and ophthalmologic (ie, fundus oculi) referrals being requested by PCP were purposely counted.

Additional measurements

The following additional information were retrieved at baseline: chronic kidney failure (code 585*), coronary artery disease/angina (codes 410-414*, excluded 412*), transient ischemic attack/stroke (codes 433-436*, 438*, 342*). Patients were also considered under pharmacological treatment if the following drugs were prescribed six month prior to the index diagnosis: metformin (ATC code: A10BA02), sulfonamides (urea derivatives: A10BB*), acarbose (A10BF01), thiazolidinediones (A10BG*), glinids (A10BX*), insulin (A10A*), combination of oral antidiabetics (A10BD*), antiplatelet drugs (B01AC04-6), statins (C10AA*) and antihypertensive drugs (C02*, C03*, C07*-9*).

Auditing process

During the follow-up two type of audits were carried out. A three-monthly internal audit, where each single PCP revised his proper records according to the aforementioned indicators, and the 6-monthly external audit, where all patients' records were reviewed and discussed by the local panel of PCPs and diabetologists. According to the study timeframe, the start-up internal audit took place in December 2006, while the external audits were withhold in November 2007 and November 2008.

By using the DECOR template, PCPs could quickly apply the following operations during the internal audit phase as well as on a daily schedule: a) to update patient's data for what concerned the indicators values; b) to extract the list of their enrolees and their related features; c) to elaborate a short report on all indicators values; d) to send information related to the entire cohort with the aim of carrying out the 6-monthly external audit intervention.

Data analysis

Continuous and categorical variables were reported as mean ± Standard Deviation (SD) and proportional values, respectively. Given the measures definition, they were estimated within the prior time window which preceded any single audit.

As a longitudinal "within-patient" study, random-effects analysis for repeated measures was adopted to test over-time changes of the indicators. All models included a random intercept to control for the observations' dependency. Therefore, Odds Ratio (OR) and related 95% Confidence Intervals (95% CIs) were estimated for each indicator by contrasting the baseline measurement with the last-audit estimate of the indicator by adjusting for any cross-sectional (from 3 to 12-monthly audits) phase. The interaction term audit x PCPs was evaluated without finding any cluster effect. Hence, this term was not retained in the final models.

The effects of internal and external audit on indicators variation were analysed by computing two separated regressions. All analyses were carried out using Stata 11.0 for Windows. A p-value < 0.05 was considered as statistically significant.

Given the clinical relevance of HbA_{1c} in diabetes, a priori sample size calculation was based on this indicator. Effective sample size was estimated as 4,150 patients (at least 25 per physician) also taking into account the possible cluster effect due to PCPs. This study was designed with a 80% power (type I error of 0.05) to detect minimum increase of 2.5%, likely due to auditing process, among patients with HbA_{1c} below than 53 mmol/mol (7%).

TABLE I.
Definition of the process and intermediate outcome measures.

Process measure	Measurement (% of patients)	Denominator Definition (n. of patients)
HA_{1c}	Two measurements/year	Total cohort (n = 4,507)
BP	Two measurements/year Three measurements/year	Total cohort (n = 4,507)
Lipid profile Total cholesterol LDL-cholesterol	 One measurement/13 months One measurement/13 months	Total cohort (n = 4,507)
Kidney function Microalbuminuria 24 h Creatinuria/Proteinuria	 One measurement/13 months One measurement/13 months	Total cohort (n = 4,507)
BMI	One measurement/year	Total cohort (n = 4,507)
Smoking habit Current		Total cohort (n = 4,507)
Cardiologic control*	One control/18 months	Total cohort (n = 4,507)
Fundus oculi	One control/18 months	Total cohort (n = 4,507)
Diabetologist referral	Two or more referrals/year	Total cohort (n = 4,507)
Intermediate outcome measure		
HA_{1c}	≥ 53 mmol/mol (7%), one measurements/year ≥ 75 mmol/mol (9%), one measurements/year Not receiving insulin	Two measurements/year (n = 2,098) One measurements/year with HbA_{1c} ≥ 75 mmol/mol (9%) (n = 427)
BP	Systolic/diastolic > 130/80 mmHg, one measurements/year Systolic/diastolic ≥ 140/90 mmHg, one measurements/year Not receiving antihypertensive drugs	Two measurements/year (n = 2,016) Two measurements/year with BP ≥ 140/90 mmHg (n = 1,161)
Lipid profile	LDL-C ≥100 mg/dL, one measurements/13 months Not receiving statins	One measurement/13 months (n = 2,084) One measurement/13 months with LDL-C ≥ 100 mg/dL (n = 325)
Kidney function	Microalbuminuria > 30 mg/dL, one measurements/13 months Not receiving RAAS medications	One measurement/13 months (n = 256) One measurement/13 months with microalbuminuria > 30 mg/dL (n = 129)
BMI	≥30 kg/m^2	One measurement/year (n = 1,996)

HbA_{1c}: Glycated Haemoglobin; BP: Blood Pressure; TC: Total Cholesterol; LDL-C: LDL Cholesterol; BMI: Body Mass Index; RAAS: Renin-Angiotensin-Aldosterone System; * Echocardiography screening.

Results

Baseline characteristics

Overall, 4,507 patients (28.3 per PCP on average) affected by T2DM were enrolled. Among them, males outnumbered females (Tab. II) and the mean age was 66.3 (± 10.3) years. Concerning co-morbidities, 2.1% and 0.8% of enrolees suffered from CKF and/or had an history of cardiovascular disease, respectively. More than one fourth of patients were treated with oral antidiabetic combinations. Specifically, 40.9% of them received metformin and 25% sulphonamides, while other antidiabetics were used in less than

TABLE II.
Baseline patients' characteristics.

Variable	n. = 4,507
Demographics	
Age (years), mean (SD)	66.3 (10.3)
Gender, female, n. (%)	2,296 (50.9)
Patients/PCP	28.3
Comorbidity	
CKF, n. (%)	94 (2.1)
Cardiovascular disease*, n. (%)	35 (0.8)
Pharmacotherapy	
Antidiabetics	
Combination of antidiabetics, n. (%)	1,021 (22.7)
Metformin, n. (%)	1,842 (40.9)
Sulfonamides, n. (%)	1,125 (25.0)
Insulin, n. (%)	391 (8.7)
Glinids, n. (%)	287 (6.4)
Thiazolidinediones, n. (%)	107 (2.4)
Acarbose, n. (%)	50 (1.1)
Other cardiovascular medications	
Antiaggregants, n. (%)	1,846 (41.0)
Statins, n. (%)	1,787 (39.7)
Antihypertensives, n. (%)	3,271 (72.6)

PCPs: Primary Care Physicians; CKF: Chronic Kidney Failure (ICD9CM: 582-7; excluded: 584); coronary artery disease/angina: 410*-414*, excluded: 412*; transient ischemic attack/stroke: 433*-436*, 438*, 342*; § insulin: ATC: A10A*; antihypertesives: C02*, C03*, C07*-9*; statins: C01AA*; ACE inhibitors: C09A*, C09B*; sartans: C09C*, C09D*; metformin: A10BA02; sulfonamides: urea derivatives: A10BB*; acarbose: A10BF01; thiazolidinediones: A10BG*; glinids: A10BX*; combination of oral antidiabetics: A10BD*; antiaggregants: B01AC04-6.

10% of patients. Other cardiovascular medications being prescribed were antihypertensives (72.6%), antiplatelets (41.0%), and lipid lowering drugs (39.7%).

Process measures

The over-time changes of each process measure were depicted in Figure 1. Almost all indicators showed a growing trend during follow-up. Specifically, the screening of HbA_{1c} and LDC-C were stably improved across the audit internal cycles. The same favourable trend was also noted for the appropriate control of kidney function, BMI and the demands of cardiology, ophthalmology and diabetology consult.

When regression analyses were carried out, HbA_{1c} monitoring was significantly higher between the first and the last audit phase (OR = 1.3; 95% CI: 1.1-1.4) and the LDL-C checking increased more than 50% during follow-up (OR = 1.6: 95% CI: 1.5-1.8). Consistently, also the indicators related to kidney function, BMI, cardiologic and ophthalmologic screening as well as diabetology referrals, grew significantly over the 5-cycle internal audits (Tab. III). Although with a reduction of the effect estimates, these results were generally confirmed when the analyses were restricted to the external 3-cycle audit.

Intermediate outcome measures

Overall, between the first to the last audit, the proportions of intermediate outcome indicators declined significantly (Fig. 2). In details, $HbA_{1c} \geq 53$ mmol/mol (ie, 7%) and 75 mmol/mol (ie, 9%) showed a sensible reduction through the 5-cycle internal audits, as well as the proportions of those outside target for LDL-C cholesterol and BMI. On the contrary, BP controls demonstrated no-meaningful changes in its trend, whereas kidney functions appeared even worsened.

When the last and the first audit were analytically compared, there was a significant reduction of those individuals with $HbA_{1c} \geq 53$ (70%) and 75 mmol/mol (50%) over the study period. Among the latter, those who were untreated with insulin were decreased by 70% in the last audit cycle. On the other hand, although there was a significant improvement in the proportions of patients achieving BP goals, the use of antihypertensives were stable after the third audit in this subgroup. Consistently, lipid profiles was improved, although the use of statins was not significantly increased (OR = 1.1; 95% CI: 0.5-2.1). Only the kidney function showed a progressive decline (OR = 3.5; 95% CI: 1.9-6.1) and the proportion of those treated with ACE inhibitors or sartans were not timely affected by both internal and external audit. Finally, the obesity degree was reduced by 30%.

As observed for process indicators, the diabetologist's intervention maintained the beneficial effects exerted by internal audits on patients' care. Indeed, the effect estimates recorded for intermediate outcome measures were somewhat lower for the external audits when compared with the internal ones (Tab. III).

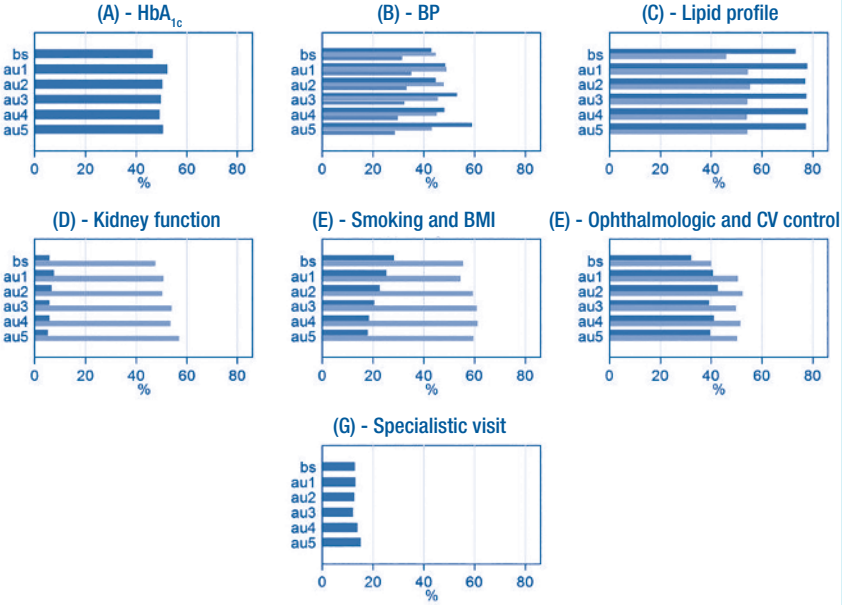
Discussion

To our knowledge, this is the first large-scale investigation aimed to translate efficacy into effectiveness of the T2DM care in a General Practice (GP) setting. The evaluation of 196 PCPs during the audit programs, showed a general improvement in the provision of 23 evidence-based indicators [10,16,17]. In specific, there was a significant growth in the level of screening for HbA_{1c}, BP, lipid profile and kidney function, as well as a significant reduction of HbA_{1c}, BP, LDL-C, defined in our study as intermediate outcome measures. Furthermore, what exerted by the specialist-integrated audits seemed to appropriately refine the records review due to solo practitioners.

Even though other surveys have shown favourable changes in quality of care of T2DM [8,18], this is the first study being performed in Europe which broadens the performance and outcome measures to

FIGURE 1.

Process indicators adherence over the 5-audit cycle.



bs: baseline; au: audit; CV: cardiovascular; HbA_{1c}: 6-monthly measurement **(A)**; BP: 6-monthly measurement (1st bar), 3-monthly measurement (2nd bar), < 130/80 mmHg (3rd bar) **(B)**; lipid profile: TC (1st bar) and LDL-C (2nd bar), 13-monthly measurement **(C)**; Kidney function: microalbuminuria (1st bar) and creatinuria/proteinuria (2nd bar), 13-monthly measurement **(D)**; BMI (1st bar), 12-monthly measurement and smoking habit (2nd bar) **(E)**; Cardiologic (ie, ECG: 1st bar) and ophthalmologic (2nd bar) control, 13-monthly measurement **(F)**; diabetologist 12-monthly visit **(G)**.

lifestyles aspects and appropriate use of medications.

Herein, performance measures which changed over the audit cycles were similar to those observed in other surveys [8,11]. As reported in a clinical trial by O'Connor and co-workers [18], HbA_{1c}, BP and LDL-C screening and targeted values were improved, only when PCPs were systematically audited by an electronic-health-record supporting system. However, the magnitude of changes was quite modest probably because of the relatively good baseline quality of care. Conversely, other investigations from the US [8,19-24] failed to improve HbA_{1c}, BP and LDL-C levels while they reached a significant changes among process indicators. Two Australian studies [12,13] recorded a better level of screening for lipids and a significant reduction in HbA_{1c}, LDL-C and triglycerides. Nevertheless, the majority of their hypertensive patients were still outside target because of pharmacological undertreatment, as shown by those with hyperlipidemia. Several reasons could explain the audit inefficacy. First, the interventions were based on general prompts without patient and/or drug-specific advices. Second, the informatics tools had not been appropriately discussed and shared by PCPs, diabetologists or other healthcare providers (e.g. nurses): as a consequence, the respective weight of clinical responsibilities were not equally distributed according to an ideal workflow model. Finally, PCPs' decision was strictly limited to their proper enrolees without being sufficiently debated with colleagues [7,18].

Therefore, the major growth of 'quality of care' seen in the present study may be related to a multiple supporting system, which comprises the easy-of-use DECOR tool and a collaborative environment with diabetologists and other PCPs, who could have further facilitated the feedback of indicators information at the audit phase. These findings would be also strengthened by the lower effect size exerted by the external audits. As a longitudinal study, each cross-sectional phase is necessarily influenced by the prior intervention, so the effect due to external audits would appear reduced because it could be already explained by the prior effect combination of the PCPs and specialists' intervention. The external audit still maintained an homogeneous improvement for any PCP's behaviour, as further confirmed by the absence of a physician-related cluster effect.

The present findings also demonstrated that almost half of the cohort were not screened at the post-audit phase for HbA_{1c} and LDL-C. In addition, the possible underuse of medications among certain categories of patients merited more attention. Specifically, those hypertensive (ie, BP ≥ 140/90 mmHg) patients who stayed on therapy at the baseline were not significantly augmented over the audit cycles. These results could be partly explained by the achievement of BP target. Indeed, the over-time stability of BP indicator could be suggestive of a favourable control. Thus, an additional use of antihypertensives has been likely considered unjustified by the PCP.

Although the screening of renal function was clearly improved, the proportion of kidney-impaired patients (microalbuminuria ≥ 30 mg/dL) appeared higher over the study period. Certainly, the growing severity of the disease could explain these results, but also an inappropriate use of antihypertensives should be taken into account. Indeed, although there were few individuals to be untreated, 45% of them was still outside target in the last audit phase. Likewise, hyperlipidemic (LDL-C ≥ 100 mg/dL) patients did not seem to be treated extensively and the audit program do not appear effective in raising the prescription of lipid lowering drugs. Among PCPs these phenomenon could be mainly related to the risk of adverse drug reactions [25] which tend to be more common in chronic patients and those with more serious diseases. Also the clinical uncertainty on the guidelines contents may underlie the reluctance to apply adequate treatment strategies. However, the concern of patients' compliance cannot be neglected. The issue of low adherence to antihypertensives has been already demonstrated by several studies [26], and the audit process could not be sufficiently effective in correcting this aspect.

TABLE III.

Over-time changes of the performance measures according to the 5-cycle internal or 3-cycle external audit.

			OR (95% CI)*	OR (95% CI)
	Baseline n. (%)	Post-audit° n. (%)	Internal audit	External audit
Process measures				
HbA_{1c}	2,098 (46.5)	2,283 (50.7)	1.3 (1.1-1.4)	1.1 (0.9-1.1)
BP				
6-monthly	2,016 (44.7)	1,946 (43.2)	0.9 (0.8-1.0)	0.7 (0.8-0.9)
4-monthly	1,432 (31.8)	1,287 (28.5)	0.8 (0.7-0.9)	0.8 (0.7-0.9)
Lipid profile				
Total cholesterol	3,308 (73.4)	3,485 (77.3)	1.4 (1.2-1.5)	1.1 (0.9-1.1)
LDL-cholesterol	2,084 (46.2)	2,444 (54.2)	1.6 (1.5-1.8)	1.1 (1.0-1.2)
Kidney function				
Microalbuminuria 24 h	256 (5.7)	228 (5.1)	0.8 (0.6-1.1)	0.7 (0.5-0.8)
Creatinuria/Proteinuria	2,144 (47.6)	2,569 (57.0)	1.7 (1.5-1.9)	1.4 (1.2-1.5)
BMI	1,996 (44.3)	2,691 (59.7)	1.2 (1.1-1.4)	1.1 (1.0-1.1)
Smoking habit				
Current	544 (12.1)	576 (12.3)	1	1
Former	2,675 (59.3)	3,123 (66.4)		
No smokers	1,288 (28.6)	808 (17.3)	1.2 (0.9-1.4)	1.1 (0.9-1.3)
Cardiologic control**	1,088 (40.1)	2,274 (50.5)	1.9 (1.7-2.1)	1.1 (1.1-1.3)
Ophthalmologic control	1,453 (32.2)	1,789 (39.7)	1.6 (1.5-1.8)	1.1 (1.0-1.2)
Diabetologist referral	583 (12.9)	685 (15.2)	1.3 (1.1-1.5)	-
Intermediate outcome measures				
HbA_{1c}				
≥ 53 mmol/mol (7%)	1,567 (74.7)	1,326 (58.1)	0.3 (0.2-0.4)	0.6 (0.6-0.7)
≥ 75 mmol/mol (9%)	427 (20.4)	325 (14.2)	0.5 (0.4-0.6)	0.7 (0.3-0.9)
≥ 75 mmol/mol 9%, no insulin treated	300 (70.3)	203 (62.5)	0.3 (0.1-0.5)	0.4 (0.2-0.7)
BP				
>130/80 mmHg	1,615 (80.1)	1,297 (66.7)	0.4 (0.4-0.5)	0.6 (0.5-0.7)
≥140/90 mmHg	1,161 (57.6)	876 (45.0)	0.5 (0.5-0.6)	0.7 (0.6-0.7)
≥140/90 mmHg, no antihypertensive treated	90 (7.8)	56 (6.4)	0.7 (0.4-2.1)	0.8 (0.5-2.2)
LDL-C				
≥ 100 mg/dL	325 (15.6)	219 (9.0)	0.4 (0.3-0.5)	0.6 (0.5-0.7)
≥ 100, no statins treated	164 (50.5)	112 (51.4)	1.1 (0.5-2.1)	0.8 (0.4-1.3)
Microalbuminuria/proteinuria				
> 30 mg/dL	129 (50.4)	156 (68.4)	3.5 (1.9-6.1)	1.1 (0.7-1.6)
> 30 mg/dL or proteinuria, no RAAS medications treated	97 (75.2)	122 (78.1)	2.8 (0.9-8.6)	1.8 (0.8-4.0)
BMI				
≥ 30 kg/m^2	897 (45.0)	786 (43.3)	0.7 (0.6-0.9)	0.8 (0.7-0.9)

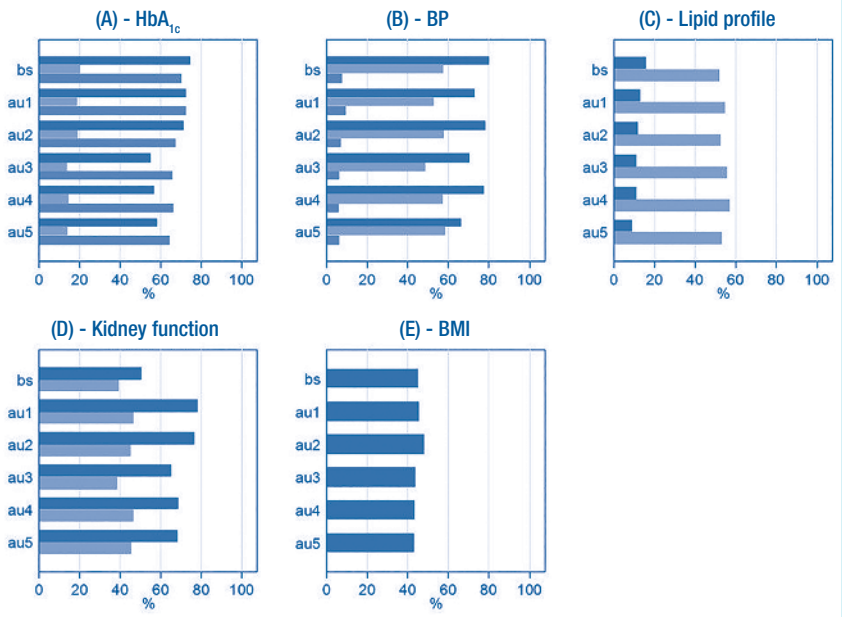
HbA_{1c}: Glycated Haemoglobin; BP: Blood Pressure; TC: Total Cholesterol; LDL-C: LDL Cholesterol; BMI: Body Mass Index; RAAS: Renin-Angiotensin-Aldosterone System; *: adjusted by intermediate audit phases; °: last internal audit; **: echocardiography screening.

On the other hand, the care of body weight was increased both in terms of screening and reduction of obesity degree. This result demonstrated a promising effect towards lifestyle issues, which were not effectively reached by prior corrective attempt [8,27].

On this regard, smoking habits were not modified by the audit cycles. As confirmed

FIGURE 2.

Intermediate outcome indicators adherence over the 5-audit cycle.



bs: baseline; au: audit; HbA_{1c}: ≥ 53 mmol/mol (7%: 1st bar), ≥ 75 mmol/mol (9%: 2nd bar), ≥ 75 mmol/mol no treated with insulin (3th bar), 12-monthly measurement **(A)**; BP: > 130/80 mmHg (1st bar), ≥ 140/90 mmHg (2nd bar), ≥ 140/90 mmHg no treated with antihypertensives (3th bar), 6-monthly measurement **(B)**; lipid profile: TC ≥ 100 mg/dL (1st bar), TC ≥ 100 mg/dL no treated with statins (2nd bar), 13-monthly measurement **(C)**; Kidney function: microalbuminuria > 30 mg/dL (1st bar), microalbuminuria > 30 mg/dL treated with ACE inhibitors and sartans (2nd bar), 13-monthly measurement **(D)**; BMI ≥ 30, 12-monthly measurement **(E)**.

by prior investigations, the absence of a more complex intervention in conjunction with a psychological support appears the most plausible explanation for these results. In fact, the smoking habit is often a lifetime issue, and a more extensive follow-up should be needed to collect reliable data with which to implement a long-term and proficient intervention [28].

Though there is room for improvement, these findings confirm that a cyclic patients' re-analysis could play an effective role in increasing the proper management of Patients with T2DM [29,30].

Almost all indicators, even if not significant, showed an ameliorating trend. Particularly, the improvement of outcome indicators concerning HbA_{1c}, BP and LDL-C sounds encouraging, because it implies a major awareness of those risk factors which can substantially modify the risk of cardiovascular complications of diabetes.

This study has some limitations. First, a cycle audit study was carried out according to pre-postintervention design without the use of randomization and a control group. As a consequence, it cannot be fully exclude that regression towards mean and other clinical factors (ie, natural disease development and its seriousness) accounts for some of the quality improvements here reported. Second, although PCPs were instructed to include all consecutive patients who suffer from T2DM according to specific inclusion criteria, patients more prone to follow PCP's indications could have been preferentially selected. That is, the potential exists for selection bias. Nevertheless, given the magnitude of change for most indicators over the study period, regression towards mean and selection bias are unlikely to constitute the entire explanation for the overall improvement of patient's care. Third, the length of the available follow-up could not be sufficient in producing an adequate effect size on smoking habits, even if the improvement of the BMI-related indicators should be suggestive of a better lifestyle in a long-term fashion.

Conclusions

In spite of limitations, this study reveals that auditing PCPs may result in improved T2DM patient's management. Reassuringly, the diabetologist's audit simply refined the patients' care operated by solo PCPs. Nevertheless, the use of certain medications should be more carefully evaluated in patients with diabetes, so aiming at reducing the risk of cardiovascular complications and kidney failure.

Given the growing prevalence of T2DM in western countries, prevention of its related disorders could have a major effect on patients' well-being and healthcare costs. In the light of the additional room for improvement seen in the post-audit phase, further amends of the intervention program among PCPs should be considered pivotal for the future research.

Conflict of interests

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References

1 Zimmet P, Alberti KG, Shaw J. *Global and societal implications of the diabetes epidemic*. Nature 2001;414:782-7.

2 Rosenbloom AL, Joe JR, Young RS, et al. *Emerging epidemic of type 2 diabetes in youth*. Diabetes Care 1999;22:345-54.

3 King P, Peacock I, Donnelly R. *The UK prospective diabetes study (UKPDS): clinical and therapeutic implications for type 2 diabetes*. Br J Clin Pharmacol 1999;48:643-8.

4 Zimmet PZ. *The pathogenesis and prevention of diabetes in adults. Genes, autoimmunity, and demography*. Diabetes Care 19995;18:1050-64.

5 Saydah SH, Fradkin J, Cowie CC. *Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes*. JAMA 2004;291:335-42.

6 Saaddine JB, Cadwell B, Gregg EW, et al. *Improvements in diabetes processes of care and intermediate outcomes: United States, 1988-2002*. Ann Intern Med 2006;144:465-74.

7 O'Connor PJ, Bodkin NL, Fradkin J, et al. *Diabetes performance measures: current*

status and future directions. Diabetes Care 2011;34:1651-9.

8 Landon BE, Hicks LS, O'Malley AJ, et al. *Improving the management of chronic disease at community health centers*. N Engl J Med 2007;356:921-34.

9 Jamtvedt G, Young JM, Kristoffersen DT, et al. *Does telling people what they have been doing change what they do? A systematic review of the effects of audit and feedback*. Qual Saf Health Care 2006;15:433-6.

10 Burgers JS, Bailey JV, Klazinga NS, et al. *Inside guidelines: comparative analysis of recommendations and evidence in diabetes guidelines from 13 countries*. Diabetes Care 2002;25:1933-9.

11 McCraw WM, Kelley PW, Righero AM, et al. *Improving compliance with diabetes clinical practice guidelines in military medical treatment facilities*. Nurs Res 2010;59:S66-74.

12 Wheatland B, Porter C, Gilles M, et al. *Initiating a PDSA cycle - improving management of diabetes in rural WA.* Aust Fam Physician 2006;35:650-2.

13 Porter C, Greenfield C, Larson A, et al. *Improving GP diabetes management - A PDSA audit cycle in Western Australia*. Aust Fam Physician 2009;38:939-44.

14 Lainscak M. *Implementation of guidelines for management of heart failure in heart failure clinic: effects beyond pharmacological treatment*. Int J Cardiol 2004;97:411-6.

15 Hobbs FD, Kenkre JE, Roalfe AK, et al. *Impact of heart failure and left ventricular systolic dysfunction on quality of life: a cross-sectional study comparing common chronic cardiac and medical disorders and a representative adult population*. Eur Heart J 2002;23:1867-76.

16 Basevi V, Di Mario S, Morciano C, et al. *Comment on: American Diabetes Association. Standards of Medical Care in Diabetes 2011*. Diabetes Care 2011;34(Suppl. 1):S11-S61.

17 De Micheli AML. *Gli standard italiani per la cura del diabete mellito 2009-2010. Uno strumento di riferimento e lavoro. Aggiornamento e formazione in Diabetologia e Malattie Metaboliche*. Rivista SIMG 2010.

18 O'Connor PJ, Sperl-Hillen JM, Rush WA, et al. *Impact of electronic health record clinical decision support on diabetes care: a randomized trial*. Ann Fam Med 2011;9:12-21.

19 Ziemer DC, Doyle JP, Barnes CS, et al. *An intervention to overcome clinical inertia and improve diabetes mellitus control in a primary care setting: improving primary care of African Americans with diabetes (IPCAAD) 8*. Arch Intern Med 2006;166:507-13.

20 Montori VM, Dinneen SF, Gorman CA, et al. *The impact of planned care and a diabetes electronic management system on community-based diabetes care: the Mayo Health System Diabetes Translation Project*. Diabetes Care 2002;25:1952-7.

21 Meigs JB, Cagliero E, Dubey A, et al. *A controlled trial of web-based diabetes disease management: the MGH diabetes primary care improvement project.* Diabetes Care 2003;26:750-7.

22 Peterson KA, Radosevich DM, O'Connor PJ, et al. *Improving diabetes care in practice: findings from the TRANSLATE trial*. Diabetes Care 2008;31:2238-43.

23 Grant RW, Wald JS, Schnipper JL, et al. *Practice-linked online personal health records for type 2 diabetes mellitus: a randomized controlled trial*. Arch Intern Med 2008;168:1776-82.

24 Crosson JC, Stroebel C, Scott JG, et al. *Implementing an electronic medical record in a family medicine practice: communication, decision making, and conflict*. Ann Fam Med 2005;3:307-11.

25 Zhang M, Holman CD, Price SD, et al. *Comorbidity and repeat admission to hospital for adverse drug reactions in older adults: retrospective cohort study*. BMJ 2009;338:a2752.

26 Mazzaglia G, Ambrosioni E, Alacqua M, et al. *Adherence to antihypertensive medications and cardiovascular morbidity among newly diagnosed hypertensive patients*. Circulation 2009;120:1598-605.

27 McDermott RA, McCulloch BG, Campbell SK, et al. *Diabetes in the Torres Strait Islands of Australia: better clinical systems but significant increase in weight and other risk conditions among adults, 1999-2005*. Med J Aust 2007;186:505-8.

28 Haug S, Meyer C, Ulbricht S, et al. *Need for cognition as a predictor and a moderator of outcome in a tailored letters smoking cessation intervention.* Health Psychol 2010;29:367-73.

29 Gannon M, Qaseem A, Snow V. *Community-based primary care: improving and assessing diabetes management*. Am J Med Qual 2010;25:6-12.

30 Tan F, Liew SF, Chan G, et al. *Improving diabetes care in a public hospital medical clinic: report of a completed audit cycle*. J Eval Clin Pract 2011;17:40-4.