Implementation of "Chronic Care Model" for Diabetes Care in Iranian Primary Health Care: Does it work?

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Abstract

Objective: Traditional health care systems were not capable to face successfully with chronic diseases including diabetes mellitus. In this regard, the Chronic Care Model or CCM was created to promote quality of care. The aim of this study was to examine whether establishment of chronic care model, with focus on diabetic patients, has led to clinically significant outcomes in Iran.

Materials and Methods: The samples were confirmed type 2 diabetes patients who had been attending to 20 CCM-based clinics in Tehran for at least one year. Repeated measurements of the same variable (including demographic, anthropometric and biochemical variables) on the same individual in 5 serial time points were used.

Results: Totally, 7190 patients (4793 females and 2397 males) with the mean age of 56 years old fulfilled inclusion criteria and entered the study. HbA1c (*P*-value: 0.001), fasting blood sugar (*P*-value: 0.001), systolic and diastolic blood pressures (*P*-value: 0.001), low density lipoprotein (*P*-value: 0.001), total cholesterol (*P*-value: 0.001), triglyceride (*P*-value: 0.001), and body mass index (*P*-value: 0.001) have significantly decreased during 4 measurement intervals.

Conclusion: Implementation of CCM frame in primary health care clinics as the first model-based participatory care has been relatively successful in the field of diabetes management in Iran. Our findings support the idea that multifaceted interventions provided through a collaborative team work could relieve various health risk factors in diabetics.

Keywords: Chronic care model, Diabetes, Repeated measure analysis

Introduction

Traditional health care systems had been basically developed to take care about acute illnesses and were not capable to face successfully with chronic diseases including diabetes mellitus (1). Diabetes has no definite cure yet and affected patients should live with it for the rest of their lives (2). Since it can leave several undesirable impacts on health if left untreated, scientists have put their efforts to develop a health care system which can be responsive to long term needs of patients. In this regard, Wagner and colleagues constructed a model of chronic illness management called “the Chronic Care Model”

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or CCM in order to promote quality of care and resulting outcomes. CCM consists of six main components: 1- delivery system redesign, consisting of role assignment for each profession in care team, scheduling regular visits and follow up and proper specialist referral system, which brings the opportunity of efficient interactions; 2- self-management support in order to train patients to participate in their own disease management; 3- decision support for medical practitioners to help them make evidence-based decisions; 4- clinical information system that makes patients' data accessible to heath care providers; 5- health care organization improvement through creating a culture and developing mechanisms that promote safe and high quality care; 6- community linkages for mobilizing community resources and using them to satisfy patients' needs (1,3).

CCM based interventions endeavor to create a "productive interaction between informed activated patient and prepared proactive practice team" (4). American Diabetes Association (ADA) in the latest version of "standards of medical care in diabetes" has strongly recommended that diabetic patients should be provided with the medical care which is adapted to the components of CCM (5).

There is some evidence that CCM-based interventions have been widely implemented to arrange improved care for chronic illness management especially diabetes around the world mainly in developed countries and promising results have been achieved (3,6).

Although it has been tried to implement CCM-based clinics within the primary health care system of Iran, there is no evidence regarding its effectiveness. Therefore, through this study, we decided to examine whether establishment of chronic care model, with focus on diabetic patients, has led to clinically significant outcomes in covered urban population in Iran.

Materials and Methods

CCM elements implementation

Tehran University of Medical Sciences (TUMS) started to implement CCM through providing care for diabetes, hypertension, hyperlipidemia and overweight / obesity in 20 clinics of Tehran province during 2010-2012. The participants of this program are all individuals older than 30. In first visit, a comprehensive medical history and physical examination was taken and lab testing for diagnosis of diabetes and hyperlipidemia was requested. If the client was healthy, a reexamination was planned to be performed after 3 years. Otherwise, he/she became a patient under medical supervision, and appropriate healthcare was provided through planned visits.

Four out of six aforementioned CCM dimensions have been running in our clinics from the beginning until now:

- Delivery system redesign: In each center, a health care provider team consisting of a general practitioner, a nurse, a nutritionist and a secretory (coordinator) were responsible for delivering care to patients. Care related tasks were well defined and distributed among team members and they interact with each other in order to ensure effective care delivery. In addition, in each visit, the next appointment was scheduled and patients would be reminded if they forget to attend the clinic through a telephone call.
- Decision support: In order to assist heath care providers in CCM clinics, some service delivery tools (SDTs) was developed. In order to create these tools, all guidelines in the field of diabetes, hypertension and hyperlipidemia were reviewed and their recommendations were extracted and adapted to the context of health system in Iran. These tools help our physicians to recognize best actions for each patient in each visit.
- Clinical information system: In order to record patients' data systematically, software was developed in Microsoft office

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Excel using VBA. The main features of this software were outlined below:

1- Patients' data including demographic characteristics, anthropometric measurements, laboratory test values, action type (visit, telephone call, and educational class), current action date and next action date could be recorded.

2- The software generates a daily telephone call list. This was used to remind patients on next visit in advance; remind patients who miss their appointment, and to ensure that patients who had been referred to a specialist have been visited by the referee.

3- The software generates graphs that demonstrate trends of changes of clinical and lab values like weight, FBS, HbA1c, etc. The graphs of 6 user-selected variables can be shown simultaneously to enable care providers to interpret the pathophysiologic basis of patients' clinical situation.

4- A dashboard was included in the software through which care providers and their supervisors can monitor the performance of each clinic. The number of patients who were under active care and follow-up, the number of patients who had attended educational sessions, the number of patients who had fully or partially responded to treatment were some of information demonstrated through appropriate charts in the dashboard.

- Self-management support: Care provider teams have to schedule educational sessions to improve patients' knowledge on how to approach their problem and empower them to apply proper self-care practices.

This study was registered as a research proposal in Shahid Sadoughi University of medical sciences by 3620 code.

Study design

In the present study, a repeated measurements design was adopted in which repeated measurements of the same variable on the same individual in serial time points were used to assess clinical effectiveness. In this regard, 5 time points with approximate 3 month intervals were extracted for each patient using registry software database, and the dataset required for analysis was constructed.

Study population and data source

The samples were confirmed type 2 diabetics who had been attending to CCM-based clinics for at least one year. Based on guideline, every diabetic patient, who is metabolically controlled, must be visited at least every three months and his/her clinical and biochemical variables should be measured. Therefore diabetic patients are expected to be visited at least four times other than initial visit during their first enrollment year. Accordingly, only patients who had four regular 3-month visits after initial one were included in the study. In addition to demographic variables and height, values of fasting blood sugar (FBS), HbA1c, triglyceride (TG), Total Cholesterol (TC), low density lipoprotein (LDL), HDL, systolic and diastolic blood pressures, and weight recorded in each visit were extracted for analytical purposes As body mass index (BMI) was calculated using the following formula:

$$BMI=\frac{Weight\ in\ Kg}{(Height\ in\ meter)^2}$$

Statistical analysis

In order to evaluate CCM-based care effectiveness we conducted repeated measure ANOVA using SPSS 22. Repeated measure ANOVA (RMA) is a type of analysis used to compare more than two repeated measurements on the same continuous quantitative variables over time. The advantage is the ability to control interpersonal differences which contributes to higher power (7). Means and standard deviations (SD) of aforementioned variables were reported in every time point and compared using RMA method. P-value, as an indicator of statistical significance, and Partial eta squared effect size as an indicator of practical significance were also reported. The results of effect size were interpreted according to Cohen's guideline (small: 0.01, medium: 0.06, large: 0.14) (8). Moreover, *P*-value less than 0.05 was considered significant.

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Results

Among 17339 diabetic patients who were attending CCM-based clinics, 7785 patients were our clinics' clients for more than one year. Among them, 7190 (92%) had been visited nearly every 3 months during first year of attendance. In this study, women were twice as likely as men with mean age of 55.2 and 58 years respectively (*P*-value: 0.001). Patients' data at baseline are presented in Table 1.

At first, we conducted repeated measure ANOVA among total members. The results of the RMA revealed that HBA1c, FBS, systolic and diastolic blood pressures, LDL, TC, TG and BMI significantly decreased during 4 measurement intervals. HDL had no significant changes during these periods. The effect size in the case of HBA1c and TC was large and in the case of FBS, systolic blood pressure and LDL was medium to large (Table 2). The results of paired comparisons between each 2 consecutive measurements illustrated that all variables except HDL had undergone a significant decrease from time 0 to time 1, whereas other paired comparisons mostly show non-significant alterations.

After that, because women were twice as likely as men and sex could be a potential confounder, we stratified data based on sex and compared 5 consecutive measurements between males and females using RMA. The results illustrated that difference between men and women was significant in BMI, lipid profile (except TG) and blood pressure as women had higher BMI and blood lipids level and lower blood pressure. However, the pattern of change did not seem to be significantly different between both sexes (Table 3).

Discussion

Implementation of CCM frame is the first experiment of model-based participatory care in the field of non-communicable diseases, delivered in primary health care centers and at the community level, in urban regions in Iran (9).

After Islamic revolution in 1979, implementation of primary health care (PHC) was the most prominent reform in the health system of Iran. PHC had mainly focused on maternal and child health as well as communicable diseases and environmental health, and attained great achievements especially in rural regions. In spite of PHC success in some dimensions of health care, health system had gradually encountered new challenges resulting from population size expansion and aging along with epidemiological transition towards dominance of non-communicable diseases (10). In such situation that PHC could not work properly and effectively, health system policymakers considered new ways of facing with such

Table 1. Patients' demographic and clinical characteristics

Variable	Category	Frequency (%) or Mean (± SD)
Age		56 (± 10)
Gender	Female	4793 (67)
	Male	2397 (33)
Marital status	Married	6316 (87.8)
	Single	44 (0.6)
	Widow	746 (10.4)
	Divorced	52 (0.7)
Education	Illiterate	2685 (37.3)
	Under high school	3696 (50)
	High school/ University	877 (12.2)
Systolic BP (mmHg)		127.1 (±18.7)
Diastolic BP (mmHg)		79.6 (± 10.7)
BMI (kg/m^2)		29.7 (± 4.7)
FBS (mg/dl)		167.7 (± 67.4)
HBA1c (mg/dl)		7.95 (±1.84)
TG (mg/dl)		192 (±126.5)
TC (mg/dl)		194.5 (± 47)
LDL (mg/dl)		108 (± 36)
HDL (mg/dl)		45 (±12.5)

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difficulties through application of successful experimented models of care in other countries and eventually opted for chronic care model. They decided to implement CCM-based care initially in some primary health care units, affiliated to Tehran University of Medical Science and then to spread out in the case of successfulness. The results of data analysis in current study demonstrated the relative effectiveness of CCM-based interventions in health outcome improvement among diabetic patients. Analysis of patients' data revealed significant improvement in FBS, HBA1c, blood pressure, LDL and total cholesterol, triglyceride and BMI during one-year period follow up after admission. The final results demonstrated large effect size in the case of HbA1c and TC and medium to large ones in the case of FBS, systolic blood pressure and LDL stated that improvement of most modifiable risk factors of diabetes complications could be considered to be meaningful (11). Many researches have confirmed that interventions consisting of one or more components of CCM are capable to improve diabetes outcomes (12). There is some evidence that redesign of delivery system is the most important part of CCM in reducing HbA1c up to 0.58% and self-management education, decision support and information system lie in the following orders with 0.46, 0.44 and 0.42 percent reduction in HbA1c value (3). Despite growing body of literature in this area, there is no consistent agreement on whether multi-component interventions are superior to the single components or which sort of interventions combination results in more favorable outcomes (12). Some studies believe no more advantage in using multi versus single

Table 2. Repeated measurement changes during one-year period in diabetic patients

Variables	Baseline (Time 0)	3 month (Time 1)	6 month (Time 2)	9 month (Time 3)	12 month (Time 4)	*P*-value of change	Effect size of change
FBS (mg/dl)	166.4 (65)*	148.6 (55)	146.8 (53)	146.6 (52)	147.4 (54)	< 0.001	0.107
HBA1c	8.03 (1.8)	7.52 (1.6)	7.34 (1.5)	7.32 (1.5)	7.35 (1.5)	< 0.001	0.157
Systolic BP	127.1 (19)	123.2 (16)	123.3 (16)	123.1 (16)	123.6 (16)	< 0.001	0.065
Diastolic BP	79.6 (11)	77.3 (10)	77.2 (10)	77.1 (10)	77.4 (10)	< 0.001	0.058
TG (mg/dl)	197.6 (131)	179.3 (110)	178.6 (102)	178.5 (100)	176.4 (104)	< 0.001	0.036
TC (mg/dl)	196.3 (48)	179.7 (43)	178.5 (43)	177.7 (43)	176.8 (44)	< 0.001	0.151
LDL(mg/dl)	109.9 (36)	97.3 (34)	96.2 (34)	96.4 (33)	95.5 (33)	< 0.001	0.131
HDL(mg/dl)	44.8 (11.9)	44.7 (12.1)	44.5 (11.3)	44.7 (11.1)	45 (11.2)	0.182	-
BMI	29.76 (4.7)	29.53 (4.6)	29.45 (4.6)	29.44 (4.6)	29.40 (4.6)	< 0.001	0.052

* mean (SD)

Table 3. Sex differences in the pattern of change in RMA results

Variables	Category	Baseline (Time 0)	3 month (Time 1)	6 month (Time 2)	9 month (Time 3)	12 month (Time 4)	*P*-value	Effect size of change
FBS (mg/dl)	female	164(64)*	148(52)	147(52)	147(53)	148(54)	0.73	
	male	170(66)	148(58)	146(53)	145(51)	146(54)		
HBA1c	female	8 (1.8)	7.5(1.5)	7.3(1.5)	7.3(1.5)	7.3(1.5)	0.2	
	male	8.1(1.8)	7.6(1.6)	7.3(1.5)	7.3(1.5)	7.4(1.6)		
Systolic BP	female	126.6 (19)	122.8 (16)	122.7 (16)	122.5 (16)	122.8 (16)	< 0.001	0.004
	male	128.1 (18)	124 (16)	124.5 (16)	124.3 (16)	125.2 (16)		
Diastolic BP	female	79.4 (11)	77.2 (9.6)	76.9 (10)	76.8 (10)	77.3 (10)	0.001	0.001
	male	80 (10)	77.6 (9)	77.7 (9)	77.5 (9)	77.7 (9)		
TG (mg/dl)	female	195.2 (124)	180.1 (101)	179.6 (101)	178 (100)	176.7 (101)	0.991	
	male	202.8 (144)	177.6 (128)	176.4 (106)	177.6 (103)	175.8 (109)		
TC (mg/dl)	female	200 (46)	184.2 (44)	183.2 (43)	182 (43)	181.5 (44)	< 0.001	0.042
	male	188 (50)	170.2 (168)	168 (42)	168.3 (40)	166.6 (42)		
LDL(mg/dl)	female	112.5 (37)	99.9 (34)	98.8 (35)	98.6 (33)	97.6 (33)	< 0.001	0.024
	male	104.2 (35)	91.9 (31)	90.5 (32)	91.7 (31)	90.8 (32)		
HDL(mg/dl)	female	46.2 (12)	46.4 (12)	46.2 (11)	46.4 (11)	46.7 (11)	< 0.001	0.085
	male	41.6 (11)	40.9 (11)	40.8 (10)	41.1 (10)	41.2 (10)		
BMI	female	30.6 (5)	30.4 (5)	30.2 (5)	30.2 (5)	30.1 (5)	< 0.001	0.066
	male	28 (4)	27.8 (4)	27.8 (4)	27.8 (4)	27.8 (4)		

* mean (SD)

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dimensional interventions in diabetes management (13) but many more others are available in favor of multi-dimensional interventions (14-16). As an example, although self-management education singly could diminish HbA1c during follow up or during a short time after training, the effect does not continue to be as large in long term follow up. Moreover, self-management education seems not to be successful in blood pressure and/or lipid control in diabetic patients (17). Considering these, when self-management education delivered to diabetic patients in combination with other interventions (multiple interventions), HbA1c reduction occurs and sustains for a longer time (3). Furthermore, cardiovascular risk factors including lipid and blood pressure would be ameliorated through such multi-dimensional interventions (18, 19). Our findings also support the idea that multifaceted interventions provided through a collaborative team work could relieve various health risk factors in diabetics.

In the present study we explored that most outcome measurements changed significantly from baseline (time 0) to 3 months after admission (time 1), but the change did not continue to be significant as time passed. This phenomenon is considered as one of the limitations of repeated measurement designs called "practice or learning effect" which implies the fact that because the members of the study with repeated measurements design are the same individuals evaluated in different multiple times, they may become more practiced and experienced with the passage of time or become bored and tired of continuing the same practice (20).

In the current study, blood pressure and lipid profile changes were examined across the time in addition to fasting blood glucose and HbA1c. Hypertension and lipid disturbance induce or exacerbate micro and macro vascular impairments in diabetic patients. Therefore, controlling efforts reside on blood pressure and blood lipids are considered as valuable as blood glucose lowering interventions to prevent further complications (21). It has been previously demonstrated in the literature that important cardiovascular risk factors have not been improved satisfactorily in diabetic patients even though blood glucose control has been achieved successfully (22). The justification may be found in the routine process of diabetes care in which both health care providers and patients put their force on blood glucose control and therefore, other measurements would be ignored despite their importance in diabetes management (23). By good fortune, nearly all the outcome measures got improved during the follow up period in our study. It would be explained by the fact that our physicians use clinical management guidelines adapted to the context of Iran. In addition to the guidelines for glycemic control and management of diabetes complications, there are two more guidelines for management of hypertension and hyperlipidemia in diabetic patients. Our physicians have also been trained on how to use these guidelines and are under regular supervision. Meanwhile, registry software generates outputs that demonstrate how successful the team has been in management of hypertension and hyperlipidemia in addition to glycemic control.

The results of present study revealed that female diabetic patients had undergone higher levels of TC and LDL along with higher HDL level. Moreover, they were much more likely to be obese than men. According to the literature, diabetic females are more prone to having higher blood lipid level than diabetic males, however the reason of this difference hasn't been discovered yet (24). The justification for significant BMI difference between both genders may be that women in developing countries experience more sedentary life due to occupational pattern transition and prevailing cultural beliefs about female physical activity and accepted body shape. In such a situation, women are more vulnerable to get excess weight through higher consumption of refined carbohydrates in daily regimen of modern world (25). The pattern of

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above-mentioned variables change during 4 intervals seemed to be similar in both genders illustrated that both women and men benefit from CCM-based services equally. Because of poor development of electronic recording in PHC network, we had no access to recorded data of diabetic patients receiving conventional care. Therefor it was not possible for us to compare CCM-based care with other existing approaches for diabetes care in Iranian PHC.

Conclusions

Implementation of CCM frame in PHC clinics as the first model-based participatory care has been successful in the field of diabetes management in Iran. The results of repeated measure analysis demonstrated significant improvement in major markers of disease control in diabetic patients attending to CCM-based clinics during one-year follow up. Our findings support the idea that multifaceted interventions provided through a collaborative team work could relieve various health risk factors in diabetics. Therefore, CCM-based diabetes care can strengthen Iranian PHC and foster more effective interventions for reducing burden of non-communicable diseases in near future.

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Conflict of Interest

The authors state that they have no conflict of interest.

Ethical approval

All procedures performed in this study were in accordance with the ethical standards of Tehran University of Medical Sciences committee and with the 1964 Helsinki declaration and its later amendments.

Informed consent

In present study, we analyzed recorded routine data of our patients and there were no interventions in the study.

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