Quality of Care in Patients with Type 2 Diabetes in Iran: A 5-year retrospective study

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yahya bayazidi  
Tehran University of Medical Sciences  
ORCiD: 0000-0002-7724-9280

Majid Davari  
m-davari@tums.ac.ir  
Corresponding Author

Abbas Kebrsaezadeh  
Tehran University of Medical Sciences

Bagher Larijani  
Tehran University of Medical Sciences

Alireza Esteghamati  
Tehran University of Medical Sciences

Fatemeh Bandarian  
Tehran University of Medical Sciences

Zahra Kashi  
Mazandaran University of Medical Sciences

Nikinaz Ashrafi  
Tehran University of Medical Sciences

Adele bahar  
Mazandaran University of Medical Sciences

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Abstract

Background The object of this study was to evaluate the quality of care indicators (process- and outcome-related) in patients with type 2 diabetes using patient-level data during the last 5 years in Iran, in private and public diabetes centers in five provinces (Tehran, Isfahan, Yazd, Mazandaran, and Kurdistan).

Method Our study was a cross-sectional study carried out on patients with type 2 diabetes at 13 diabetes centers (private and public). Annual tests for hemoglobin A1C, serum lipid (LDL) and screening for nephropathy (urine protein or urine albumin quantitative test) were used to evaluate process-related and hemoglobin A1C, blood pressure and lipids levels were used to assess outcome-related outcomes. Findings Among 1976 patients, 54% were women with an average of 15 years of diabetes duration and approximately 83% of patients were obese or overweight. About 9% of patients had a hemoglobin A1C test every three months. The values obtained were favorable for controlling lipid profile but less than standard for screening for nephropathy and only about 30% of patients were within the optimal range for simultaneous control of process-related indicators. Findings for outcome-related indicators show that the achievement of blood glucose, blood pressure, and low-density lipoprotein targets were 31, 49 and 70%, respectively and concurrent achievement was 13.8% in the last year.

Conclusion The performance of the health system has much room for improvement and diabetes control programs have not been favorable in any of the provinces studied and have not led to optimal control.

Background
Studies show that the Middle East will experience the largest increase in diabetes burden among the rest of the world in the coming years. Most of this increase in diabetes will occur in the age group of 45–64 years, which are economically active population in the community. However, the situation is different in Western countries and most people with diabetes are over 65 years of age who are economically less active or inactive (1).

The prevalence of type 2 diabetes continues to increase in Iran due to population growth, aging, urbanization, obesity, and inactivity (2, 3). The prevalence of diabetes in Iran is estimated at 11.4% in 2011 and is still increasing (35% increase between 2005 and 2011) (4). About 40% of these patients have not yet been diagnosed (5).

Literature in this point of view is dichotomous, while some studies have shown improvement in care outcomes in type 2 diabetic patients in Iran (6), a precise literature review shows that the performance of the health care system is still far from the optimal point.

Only 6.4% of respondents had a hemoglobin A1C test last year and 25.7% stated they had a blood lipid profile test at the same time. 39.8% and 20.5% of diabetic patients had eye and foot examinations, respectively in the year leading up to the study (2009) and about 25% of patients needed to improvement in low-density lipoprotein levels and 45% of them had high blood pressure (7). Previous findings have also shown that only about 50% of diabetic patients have good blood glucose control and blood pressure and dyslipidemia control were even lower (39.9 and 46.8%) (4).

Studies have shown that high quality of care, as well as regular consultation with a physician, may reduce the risk of mortality and the occurrence of micro- and macro-
vascular complications (8–10). Therefore, it is vital to improving the quality of care, including maintaining optimal blood glucose and regular control of complications (11).

Indicators for measuring quality of care include two general categories: a) Process-related indicators (The extent of the use of a specific evidence-based care process), for example, the number of annual A1C tests and b) outcome-related indicators (reports change in the patient's condition), for instance, the percentage of patients achieving A1c-related goals (12, 13).

Unfortunately, only a few limited studies have been conducted to determine control goals in Iran, but the findings have not been sufficiently comprehensive and generalizable at the national level. On the other hand, these studies have mostly been conducted for a short period and do not reflect an understanding of the quality of care in a long time (7, 14).

This study aimed to evaluate the quality of care indicators (process and outcome) in patients with type 2 diabetes using patient-level data during the last 5 years in Iran, in private and public diabetes centers in five provinces (Tehran, Isfahan, Yazd, Mazandaran, and Kurdistan).

methods

Sampling Method

We using direct interview method to collect demographic information. Clinical information was also extracted from paper records available at diabetes centers in public hospitals and social security hospitals as well as private diabetes clinics.

We had a some reason's for choosing the cities, Tehran and Isfahan are two metropolises (23% of the total population of Iran lived in these two provinces in
2016) and also have better access to specialized health care services compared to other provinces. Yazd has the highest prevalence of diabetes (16.3%) among all provinces (31 provinces), the family physician program is running in Mazandaran and Kurdistan was one of the deprived provinces in terms of access to the care. Inclusion criteria for the patients included diagnosis of type 2 diabetes, the use of anti-diabetic medications for the past 5 years, the existence of clinical and pharmacological information for the patient over the period and ongoing referral to the relevant treatment center.

Initially, patients with type 2 diabetes who have regular visits to diabetes centers were identified and selected. The clinical information for these patients was recorded and available for at least 5 years. The subjects were selected and invited to cooperate using a random sampling method based on the patient file number (1984 Patients with type 2 diabetes). In centers where the statistical population was small, the entire statistical population was included in the study. Required information including demographic information was collected and direct interviews were performed to evaluate the validity of the items such as the number of referrals, number of diagnostic tests ... in the patients' records to extract process-related indicators. Also, data related to ABC care goals (hemoglobin A1C, Blood pressure, and low-density lipoprotein) were used to extract outcome-related indicators in these patients. This information was collected for a period of 5 years. The study was approved by the Ethics Committee (IR.TUMS.PSRC.REC.1396.1991) at Tehran University of Medical Sciences and all the patients provided written informed consent.

**Statistical analysis**

All statistical analysis was performed using Stata-Corp 2014.
Descriptive analysis was performed for each year using mean and standard deviation, for continuous variables and percentage for binary variables. One-way ANOVA was used to compare changing the means during the study period were appraised through the absolute increase of each variable and 95% CI.

**Process-related quality indicators:**

To continuously improve the patients’ clinical indicators, we extracted the following aspects:

1. Hemoglobin A1C test
2. Serum lipid test (LDL)
3. Nephropathy screening

For blood glucose control, testing hemoglobin A1C every three months was considered a standard limit based on clinical guidelines (26, 32).
For lipid profile control, serum lipids (low-density lipoprotein) testing performed at least once a year were considered appropriate.
For nephropathy screening, one or both of the following tests were considered appropriate: a urine protein test or a urine albumin test. Besides, the annual results of these tests were considered as a standard limit.
The percentage of patients with simultaneous measurement of all three variables was evaluated.

**Outcome-related quality indicators**

Randomized clinical trials in patients with type 2 diabetes have shown that controlling blood sugar, blood pressure and lipids are effective strategies to reduce the risk of complications of diabetes (8, 15-18). Also, these strategies are very cost-effective (19-21).

To measure the achievement of these indicators, we have used ABC[1] Care (12), which The American Diabetes Association (ADA) has put a lot of emphasis on the control and achievement of these triple goals.

For blood glucose control, HbA1c <7% was considered as the standard limit.
Blood pressure <130/80 mm Hg was considered as a standard limit to control blood pressure profile.
To control the lipid profile, low-density lipoprotein (LDL) <100 mg/dL was considered as the standard limit.
The percentage of patients with Simultaneous achievement of ABC care goals was evaluated.
Glycosylated Hemoglobin (HbA1c)- Blood Pressure (BP)- Low-Density Lipoprotein (LDL)

Results

Analyses and results are based on data from 1984 patients with type 2 diabetes who were collected from private and public diabetes centers in five provincial capital cities (Tehran, Isfahan, Yazd, Mazandaran, and Kurdistan). We will continue with these analyses and results (Table 1).

Table 1  
Demographic information of patients with type 2 diabetes

|                | Tehran | Isfahan | Yazd  | Kurdistan | Mazandaran | Total |
|----------------|--------|---------|-------|-----------|------------|-------|
| Female (sex percent) | 54     | 52      | 60    | 50        | 51         | 53.4  |
| Average age (years) | 62.85  | 63.45   | 60.55 | 61.7      | 63.11      | 62.33 |
| Average age (years) | 15.84  | 14.34   | 14.46 | 15.28     | 13.71      | 14.72 |
| Body Mass Index   |        |         |       |           |            |       |
| < 18.5 kg/m²      | 0.0    | 0.1     | 0.1   | 0.0       | 0.1        | 0.06  |
| 18.5-24.9 kg/m²   | 18     | 16      | 17    | 15        | 20         | 17.2  |
| 25.0-29.9 kg/m²   | 45     | 42      | 40    | 50        | 46         | 44.6  |
| ≥ 30 kg/m²        | 37     | 41.9    | 42.9  | 35        | 33.9       | 38.14 |
| Age              |        |         |       |           |            |       |
| < 45             | 5      | 10      | 7     | 6         | 9          | 7.4   |
| 45-65            | 65     | 55      | 60    | 62        | 59         | 60.2  |
| > 65             | 30     | 35      | 33    | 32        | 32         | 32.4  |

54% of the patients were female and patients’ mean diabetes age was 14.7 years. 44.6% and 38.14% of the patients were overweight and obese, respectively. 67.6% were in the age group of 25–65 years.

Only 8% of patients in 2012 and 9% in 2016 had A1C testing every three months during their illness and there were still patients in the study population who had not been tested for long-term blood glucose. The mean number of A1C tests was 1.62 times per patient in the first year and 1.89 tests in the last year.

To control the lipid profile, a serum lipid test (low-density lipoprotein cholesterol)
was performed about 1.6 times in the whole study period. For nephropathy screening, about half of the patients (46% in the first year and 42% in the final year) had done one of two urine protein or urine albumin tests, and the mean number of urine protein test was 0.5 test per year.

Simultaneous achievement of three care indicators (hemoglobin A1c test once every three months, serum lipids test (low-density lipoprotein cholesterol) at least once a year, and urine protein test or urine albumin test once a year), was about one-thousandth of the patients in the first year and 2% in the last year. Only by adjusting the hemoglobin A1C test to “one or more tests every six months”, about 30 percent of patients were within the optimal range (Table 2).
Table 2
Process-related quality indicators

| Index                                      | 2012      | 2013      | 2014      | 2015      | 2016      |
|-------------------------------------------|-----------|-----------|-----------|-----------|-----------|
| Glycemic control monitoring               |           |           |           |           |           |
| % HbA1c test (≥ 1 per three months) % (person) | 8 (158)   | 9 (178)   | 10 (198)  | 10 (198)  | 9 (178)   |
| % HbA1c test (without A1c test) % (person) | 13 (257)  | 10 (198)  | 7 (138)   | 6 (119)   | 2 (40)    |
| Mean HbA1c test (per year per patient)    | 1.62      | 1.71      | 1.82      | 1.86      | 1.89      |
| Lipid profile monitoring                  |           |           |           |           |           |
| Mean Serum lipid test (≥ 1 per year)      | 1.50      | 1.65      | 1.63      | 1.68      | 1.59      |
| % LDL test (without LDL test) % (person)  | 13 (162)  | 8 (154)   | 8 (212)   | 7 (232)   | 7 (194)   |
| Nephropathy screening                     |           |           |           |           |           |
| Urine protein test (≥ 1 per year) % (person) | 46 (911)  | 45 (887)  | 43 (847)  | 47 (938)  | 42 (821)  |
| Mean Urine protein test (per year per patient) | 0.55      | 0.54      | 0.55      | 0.61      | 0.53      |
| ALL GOALS                                 |           |           |           |           |           |
| HbA1c test (≥ 1 per three months) lipid test (≥ 1 per year) | 0.008 (15) | 0.015 (30) | 0.017 (34) | 0.018 (36) | 0.017 (38) |
| Urine protein test (≥ 1 per year)         |           |           |           |           |           |
| HbA1c test (≥ 1 per six months) lipid test (≥ 1 per year) | 0.28 (547) | 0.28 (549) | 0.30 (588) | 0.33 (652) | 0.29 (565) |

Outcome-related quality indicators

Achieving ABC Care Goals:

Table 3 shows the achievement of the blood glucose goals according to the American Diabetes Association guideline. Changes in the percentage of people below the threshold during the years 2012–2016 were as follows: For the patient population of Tehran was from 31–29% (p-value > 0.05), In Isfahan was from 31–33% (p-value > 0.05), In Yazd was from 18–24% (p-value < 0.05), In Kurdistan was from 46–40% (p-value < 0.05), In Mazandaran province was from 32–27% (p-value <
These values were 32.4% on average for the whole population and the total changes were not statistically significant. This means that there were no significant changes in the percentage of people below or above the hemoglobin A1C threshold over the 5 years.

| Year | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|------|--------|---------|------|-----------|------------|-------|
| 2012 | 0.31   | 0.31    | 0.18 | 0.46      | 0.32       | 0.324 |
| 2013 | 0.32   | 0.32    | 0.18 | 0.48      | 0.37       | 0.341 |
| 2014 | 0.32   | 0.34    | 0.2  | 0.45      | 0.33       | 0.337 |
| 2015 | 0.27   | 0.35    | 0.28 | 0.38      | 0.29       | 0.306 |
| 2016 | 0.29   | 0.33    | 0.24 | 0.4       | 0.27       | 0.312 |
| Mean | 0.3    | 0.68    | 0.22 | 0.43      | 0.31       | 0.324 |
| P for Trend | 0.068 | 0.064 | 0.038 | 0.021 | 0.001 | 0.061 |

Based on the results (Table 4), about 56% of patients had a mean blood pressure lower than the target or optimal level (lower than 130/80) in the first year and this amount reaches 49% in the last year. The percentage decreased in optimal blood pressure over a 5-year interval was statistically significant in all populations.

| Year | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|------|--------|---------|------|-----------|------------|-------|
| 2012 | 0.55   | 0.76    | 0.3  | 0.6       | 0.58       | 0.56  |
| 2013 | 0.6    | 0.75    | 0.38 | 0.6       | 0.53       | 0.57  |
| 2014 | 0.53   | 0.76    | 0.41 | 0.59      | 0.56       | 0.57  |
| 2015 | 0.48   | 0.76    | 0.37 | 0.64      | 0.45       | 0.54  |
| 2016 | 0.41   | 0.73    | 0.35 | 0.55      | 0.42       | 0.49  |
| P for Trend | 0.017 | 0.054 | 0.037 | 0.036 | 0.001 | 0.037 |

To control the lipid profile, about 70% of patients had a mean LDL below the target limit (below 100) and these values (increases) were statistically significant in all the provinces studied over 5 years (Table 5).

| Year | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|------|--------|---------|------|-----------|------------|-------|
| 2012 | 0.7    | 0.72    | 0.46 | 0.61      | 0.69       | 0.64  |
| 2013 | 0.76   | 0.76    | 0.61 | 0.57      | 0.72       | 0.68  |
| 2014 | 0.72   | 0.66    | 0.7  | 0.7       | 0.78       | 0.71  |
| 2015 | 0.76   | 0.72    | 0.73 | 0.74      | 0.78       | 0.74  |
| 2016 | 0.81   | 0.78    | 0.68 | 0.77      | 0.86       | 0.78  |
| P for Trend | 0.041 | 0.047 | 0.037 | 0.036 | 0.021 | 0.036 |
Table 6 shows the simultaneous achievement of ABC cares goals according to the ADA guideline (34). According to the findings of the study, during the years 1391-1395, simultaneous achievement of ABC care goals was 14% for Tehran province patients, 20% for Isfahan province patients, less than 1% for Yazd province patients, 19% for Kurdistan province patients and 12% for Mazandaran province patients. This value was 14% for the whole population and the overall changes were not statistically significant. This means that the percentage of achieving ABC care goals has not changed significantly over the 5 years.

| Year | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|------|--------|---------|------|-----------|------------|-------|
| 2012 | 0.16   | 0.19    | 0.03 | 0.18      | 0.12       | 0.136 |
| 2013 | 0.18   | 0.2     | 0.05 | 0.19      | 0.12       | 0.148 |
| 2014 | 0.14   | 0.19    | 0.05 | 0.19      | 0.16       | 0.146 |
| 2015 | 0.12   | 0.21    | 0.07 | 0.2       | 0.1        | 0.14  |
| 2016 | 0.1    | 0.21    | 0.06 | 0.2       | 0.12       | 0.138 |
| Mean | 0.12   | 0.194   | 0.052| 0.198     | 0.144      | 0.142 |
| P for Trend | 0.078 | 0.066 | 0.061 | 0.063 | 0.052 | 0.06 |

Discussion:

Simultaneous goals of diabetes control include reduction of blood sugar to the recommended targets through lifestyle and pharmacotherapy; evaluation and decreasing of cardiovascular risk factors (overweight / obesity, hypertension, and dyslipidemia); regular screening for micro- and macro-vascular complications (22). In this study, we attempted to investigate the levels of access to each. There are very limited studies on the quality of diabetes care in Iran and their findings are limited to specific areas.

We divided our analysis into two subtitles; process evaluation and outcome evaluation.

Process evaluation:
While previous studies showed that only 6.4% of the patients had one or more tests per year for the HBA1c (7), our results showed that 9% of our patients had an optimum number of HBA1c tests (once every three months) per year. The mean number of HbA1c tests in the entire study period was less than two tests per year per patient.

Clinical guidelines suggest that for patients who have not had a hemoglobin A1C test for the past three months or even for one year, the physician should promptly set blood glucose targets and request hemoglobin A1c testing for each subsequent visits (23). When reaching control levels, the A1c test should be repeated every 3 to 6 months, and if uncontrolled, both regular A1c testing should be performed every 3 months and with the evaluation of the patient's medication used, intensification of drug therapy should be considered (24). The findings of the study show that the number of tests performed was less than half of the international clinical standards over a period of 5 years and this number did not change statistically significantly during the study (patients without tests decreased during the study).

But these values for patients with annual LDL testing vary from 24 percent in 2006 to more than 90 percent in 2016. On average, patients performed a lipid profile test approximately 1.50 times during the study period, which was optimal. Process analysis also showed that about 58 percent of patients do not do quantitative urine protein testing annually.

The results of simultaneous achievement of three process-related care indicators (hemoglobin A1c test once every three months, serum lipids test (low-density lipoprotein cholesterol) at least once a year, and urine protein test or urine albumin test once a year), show that on average about one percent of patients have achieved simultaneous goals and by adjusting the HbA1c test to “one or more tests
every six months”, about 30 percent of patients were within the optimal range. The results show that, except for the annual LDL test, the measurement of other values was less than optimal.

Outcome evaluation:
Concerning the quality of care outcomes, the results of internal studies have shown different results, mainly due to the year of study and the sample population composition (age of diabetes, type of diabetes, ...).

Blood glucose control at the beginning and the end of our study was estimated at 0.32% of the total population despite very slight fluctuations over the 5 years (decreasing trend), and the changes were not statistically significant over this period (p-value > 0.05).

The results of recent studies have shown that the average HBA1c level in the diabetic population has reached above average (8.00 ± 0.01%) in 2017 and HBA1c control has reached to 44.10% (6). However, because the results are presented for all types of diabetes in general, comparing the control results with the present study may be associated with bias.

Findings of an unpublished study in 2011 about the non-communicable disease risk factor supervision showed that 56.7% of patients had an A1c level below 7%. Also in a study of cardiovascular risk factors in type 2 diabetic patients in Mashhad, findings showed that only 25% of patients had A1c level less than 7%. The differences in these studies can be related to the sampling method and patients’ diabetes age, which may support the hypothesis that with increasing diabetes age, their blood glucose control status worsens (26). Accepting these findings, it should be noted that many studies have shown that not only the age of diabetes diagnosis not the main cause of inadequate control findings but control status had a
statistically significant improvement over time.

The findings of Mohammad Ali et al study over 12 years (1999–2010) showed that 44.3% of patients in the first 4 years and 52.2% of patients in the last 4 years had a hemoglobin A1c level of less than 7% (p-value ≥ 0.05) (27). Another study in the Spanish state of Catalonia between 2007 and 2013 showed that patients with hemoglobin A1c were less than 7%, from 52.2% at baseline to 55.6% at the end of the study (28). In another study in the Spanish state of Catalonia conducted between the years 2007 to 2013, findings showed that patients with hemoglobin A1c less than 7%, were from 52.2% at the beginning of the study to 55.6% at the end of the study (28).

Another study of Tehran Lipid and Glucose Study (TLGS) also found that 40.36% of men and 36.32% of women and 38.34% of the subjects on average had LDL levels of less than 100 mg/dL. Findings of the non-communicable disease risk factor supervision study (unpublished), obtained shortly after Tehran Lipid and Glucose Study (TLGS), showed that 39.9% of patients had LDL levels less than 100 mg/dL. Considering the time of publication of these studies, it can be hypothesized that patients' blood lipid levels were improving and this hypothesis was further strengthened in two published studies.

Findings of prospective analysis study on first national diabetes report from the National Diabetes Prevention and Control Program in 2015, as well as our study in 2016, conducted 5 and 6 years, respectively after the non-communicable disease risk factors supervision study, showed that around 60% and 70% (present study) of patients, respectively, had LDL levels less than 100 mg/dL.

Gradual changes in the treatment of hypertension in patients with type 2 diabetes, from the classic target blood pressure of less than 90/140 mmHg to more intensive
blood pressure control (80/130 mmHg), have been affected by several major clinical trials. Evidence specifically indicates that a further reduction in blood pressure (to 130/80 mmHg) is possible in diabetic patients (29) and may lead to a significant reduction in cardiovascular complications in these groups of patients undergoing more intensive blood pressure treatment (29-31).

Various Iranian internal studies have shown that blood pressure is controlled by 40–50% (less than 130/80 mmHg) and these values for our study show that 55% of patients have achieved optimal goals on average. These values show a higher optimal level than most previous studies in Iran, but in our study patients with optimal blood pressure decreased during the study period, from 56% in 2012 to 49% in 2016 and these changes were statistically significant.

The findings of our study showed that about 14.2% of patients were able to achieve control goals simultaneously. This value was 13.6% at the beginning of the study, but the reported increase was not statistically significant (p-value > 0.05).

The findings of the study by Mohammad Ali et al. over 12 years (1999–2010) showed an increasing trend (4.6% in 2000, 9.5% in 2004, and 14.3% in 2010). In another study conducted to evaluate the simultaneous achievement of control goals between 1988 and 2010, the percentages of people with simultaneous achievement of control goals were 1.7%, 7.1% and 18.8% between years 1988-1994, 1995-2002, 2003-2006, and 2007-2010, respectively; and these changes were significant at all these intervals (32).

Among process-related care, optimal control has only been performed on the number of paraclinical tests for blood lipid levels, and the results of the study also show optimal outcomes for blood LDL levels, but in other cares, the results for the processes and their outcomes were undesirable.
Control level was not optimal at both process and outcome levels (at the process level, 30% of patients and at the outcome level, 13.8% of patients were in a desirable condition).

Different factors can be involved in the optimal control of diabetes that lack of multi-factor control can lead to undesirable results:

Overall, 83% of patients were overweight and obese, according to our study, and obesity alone or in combination with uncontrolled hemoglobin A1C, systolic and diastolic blood pressure, and LDL-cholesterol are a risk factor for microvascular and neuropathic complications in diabetic patients (33)

In addition, today's clinical guidelines not only generally state that patients who cannot reach the goals set for hemoglobin A1c should be followed up every 2–3 times to regulate treatment but also indicate that clinical judgment should be performed individually for each individual (34–39 and in patients with undesirable conditions, urgent attention should be paid to prompt and consistent treatment (40).

Researches have shown that approximately 50% of patients with type 2 diabetes achieve A1c levels below 7% (appropriate control according to ADA) with oral monotherapy for 3 years (41–46). This disappointing result is partly due to the delay in initiating the first drug treatment after reaching A1c levels above expected levels (47). This outcome may also be due to delayed timely diagnosis of pre-diabetic or diabetic patients, and also is largely due to the actions of specialist and primary care physicians who do not perform well early interventions, and thus, the critical window of treatment for effective disease management is often missed (44).

Despite a large number of guidelines for type 2 diabetes, studies have shown that many physicians do not have adequate information about existing clinical guidelines
for type 2 diabetes. In one of these studies, only 39.8% of physicians participated in a continuous improvement program for diabetes management, and 52% of general practitioners were aware of the therapeutic targets for HbA1c (17). Another study showed that only 29% of physicians had adequate information about existing guidelines (41). A study of knowledge and attitudes in 8 countries found that 51% of patients had never heard of HgA1c before and more than 10% of physicians measured it once a year (44).

Before focusing on structured guidelines that emphasize more on the HgA1c recommended targets in different countries, diabetes management with Hypoglycemic Medications was often inadequate and appropriate changes in drug regimens were only made when A1C levels were above 9% (41, 43, 48). Poor blood glucose management and subsequent failure to achieve HbA1c target levels are often clinically related to physician inertia (failure to initiate therapy or to intensify or change therapy inpatients) and may inappropriately set personalized goals (49).

Although the efficacy of most insulins has been proven in several studies compared to most oral medications (50-53) and most patients with type 2 diabetes require insulin to maintain HbA1c levels less than 7%, about nine years after diagnosis (46) the share of insulin use, in 2016, was only 25% of the total anti-diabetic medications use (insulin pens have been covered by insurance in Iran since 2012). The findings of the study also showed that, between 2012 and 2016, there was no significant change in the pattern of antidiabetic medications use (54) while the share of insulin in total anti-diabetic medications use was more than 40% in Sweden, Norway, Germany, Denmark and the UK (55).

Conclusion
The findings of the study showed that diabetes control programs were not favorable in any of the studied provinces and did not lead to optimal control.

The results of simultaneous achievement of the three process-related indicators of care indicate that on average only about 30% of patients perform clinical guidelines routine tests. The findings show that, except for the annual LDL measurement, other indicators were less than optimal.

Findings showed that total HbA1c changes were not statistically significant in the whole population and the percentage of patients with optimal blood pressure was statistically significantly reduced in all studied provinces over a period of 5 years. About 30% of patients had an average LDL greater than the determined limit (below 100), and the percentage of simultaneous achievement of ABC care goals over the five years did not change significantly.

Also, there was no significant change in the pattern of antidiabetic medications use between 2012 and 2016 in the study population, with insulin use showing only a 5% increase. At the end of the study, the prescription of different types of insulin reached 25% of all antidiabetic medications.

The results are presented for the mean of services and care provided in diabetes centers under study and the results cannot be generalized as single comparisons.

Abbreviations
HbA1c (Hemoglobin A1c)
Glycated hemoglobin
LDL
low-density lipoproteins
BP
Blood Pressure
BMI
Body Mass Index
ABC
A1C, Blood Pressure and Cholesterol

declarations

- Ethics approval and consent to participate
The study was approved by the Ethics Committee IR.TUMS.PSRC.REC.1396.1991) at Tehran University of Medical Sciences and all the patients provided written informed consent.

- Consent to publish
available from the corresponding author on reasonable request.

- Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

- Competing interests
The authors declare that they have no competing interests

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- Authors' Contributions
All authors read and approved the final manuscript

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tables

Table 1. Demographic information of patients with type 2 diabetes

|                      | Tehran | Isfahan | Yazd   | Kurdistan | Mazandaran | Total  |
|----------------------|--------|---------|--------|-----------|------------|--------|
| Female (sex percent) | 54     | 52      | 60     | 50        | 51         | 53.4   |
| mean diabetic age (years) | 15.84 | 14.34   | 14.46  | 15.28     | 13.71      | 14.72  |
| Average age (years)   | 62.85  | 63.45   | 60.55  | 61.7      | 63.11      | 62.33  |
| Body Mass Index       |        |         |        |           |            |        |
| <18.5 kg/m²           | 0.0    | 0.1     | 0.1    | 0.0       | 0.1        | 0.06   |
| 18.5 - 24.9 kg/m²     | 18     | 16      | 17     | 15        | 20         | 17.2   |
| 25.0-29.9 kg/m²       | 45     | 42      | 40     | 50        | 46         | 44.6   |
| ≥30 kg/m²             | 37     | 41.9    | 42.9   | 35        | 33.9       | 38.14  |
| Age                   |        |         |        |           |            |        |
| <45                   | 5      | 10      | 7      | 6         | 9          | 7.4    |
| 45-65                 | 65     | 55      | 60     | 62        | 59         | 60.2   |
| >65                   | 30     | 35      | 33     | 32        | 32         | 32.4   |

Table 2. Process-related quality indicators
## Glycemic control monitoring

| Index                                      | 2012 | 2013 | 2014 | 2015 | 2016 |
|-------------------------------------------|------|------|------|------|------|
| % HbA1c test (≥1 per three months) %(person) | 8 (158) | 9(178) | 10(198) | 10(198) | 9(178) |
| % HbA1c test (without A1c test) %(person) | 13(257) | 10(198) | 7(138) | 6(119) | 2(40) |
| Mean HbA1c test (per year per patient)    | 1.62 | 1.71 | 1.82 | 1.86 | 1.89 |

## Lipid profile monitoring

| Index                                      | 2012 | 2013 | 2014 | 2015 | 2016 |
|-------------------------------------------|------|------|------|------|------|
| Mean Serum lipid test (≥1 per year)       | 1.50 | 1.65 | 1.63 | 1.68 | 1.59 |
| % LDL test (without LDL test) %(person)   | 13(162) | 8(154) | 8(212) | 7(232) | 7(194) |

## Nephropathy screening

| Index                                      | 2012 | 2013 | 2014 | 2015 | 2016 |
|-------------------------------------------|------|------|------|------|------|
| Urine protein test (≥1 per year) %(person) | 46(911) | 45(887) | 43(847) | 47(938) | 42(821) |
| Mean Urine protein test (per year per patient) | 0.55 | 0.54 | 0.55 | 0.61 | 0.53 |

## ALL GOALS

| Index                                      | 2012 | 2013 | 2014 | 2015 | 2016 |
|-------------------------------------------|------|------|------|------|------|
| HbA1c test (≥1 per three months)          | 0.008 (15) | 0.015 (30) | 0.017 (34) | 0.018 (36) | 0.017 (38) |
| lipid test (≥1 per year)                  |      |      |      |      |      |
| Urine protein test (≥1 per year)          | 0.28 (547) | 0.28 (549) | 0.30 (588) | 0.33 (652) | 0.29 (565) |

## Table 3. ABC care (targets for HbA1c)

| A1c< 7 | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|--------|--------|---------|------|-----------|------------|-------|
| Year   |        |         |      |           |            |       |
| 2012   | 0.31   | 0.31    | 0.18 | 0.46      | 0.32       | 0.324 |
| 2013   | 0.32   | 0.32    | 0.18 | 0.48      | 0.37       | 0.341 |
| 2014   | 0.32   | 0.34    | 0.2  | 0.45      | 0.33       | 0.337 |
| 2015   | 0.27   | 0.35    | 0.28 | 0.38      | 0.25       | 0.306 |
| 2016   | 0.29   | 0.33    | 0.24 | 0.4       | 0.27       | 0.312 |
| Mean   | 0.3    | 0.68    | 0.22 | 0.43      | 0.31       | 0.324 |
| P for Trend | 0.068 | 0.064 | 0.038 | 0.021 | 0.001 | 0.061 |
Table 4. ABC care (targets for BP)

| Year | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|------|--------|---------|------|-----------|------------|-------|
| 2012 | 0.55   | 0.76    | 0.3  | 0.6       | 0.58       | 0.56  |
| 2013 | 0.6    | 0.75    | 0.38 | 0.6       | 0.53       | 0.57  |
| 2014 | 0.53   | 0.76    | 0.41 | 0.59      | 0.56       | 0.57  |
| 2015 | 0.48   | 0.76    | 0.37 | 0.64      | 0.45       | 0.54  |
| 2016 | 0.41   | 0.73    | 0.35 | 0.55      | 0.42       | 0.49  |
| P for Trend | 0.017 | 0.054 | 0.037 | 0.036 | 0.001 | 0.037 |

Table 5. ABC care (targets for LDL)

| Year | Tehran | Isfahan | Yazd | Kurdistan | Mazandaran | Total |
|------|--------|---------|------|-----------|------------|-------|
| 2012 | 0.7    | 0.72    | 0.46 | 0.61      | 0.69       | 0.64  |
| 2013 | 0.76   | 0.76    | 0.61 | 0.57      | 0.72       | 0.68  |
| 2014 | 0.72   | 0.66    | 0.7  | 0.7       | 0.78       | 0.71  |
| 2015 | 0.76   | 0.72    | 0.73 | 0.74      | 0.78       | 0.74  |
| 2016 | 0.81   | 0.78    | 0.68 | 0.77      | 0.86       | 0.78  |
| P for Trend | 0.041 | 0.047 | 0.037 | 0.036 | 0.021 | 0.036 |

Table 6. Simultaneous achievement of ABC care goals
| Year | LDL<100 | BP<130/80 | HbA1c<7 |
|------|---------|-----------|---------|
|      | Tehran  | Isfahan   | Yazd    | Kurdistan | Mazandaran | Total |
| 2012 | 0.16    | 0.19      | 0.03    | 0.18      | 0.12       | 0.136 |
| 2013 | 0.18    | 0.2       | 0.05    | 0.19      | 0.12       | 0.148 |
| 2014 | 0.14    | 0.19      | 0.05    | 0.19      | 0.16       | 0.146 |
| 2015 | 0.12    | 0.21      | 0.07    | 0.2       | 0.1        | 0.14  |
| 2016 | 0.1     | 0.21      | 0.06    | 0.2       | 0.12       | 0.138 |
| Mean | 0.12    | 0.194     | 0.052   | 0.198     | 0.144      | 0.142 |
| P for Trend | 0.078 | 0.066     | 0.061   | 0.063     | 0.052      | 0.06  |