

## The Effect of Quality of Care on Cardiovascular Risk Factors in Newly Diagnosed Diabetic Patients

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### ABSTRACT

**Background:** In this study, we evaluated the quality of care and control of cardiovascular risk factors in newly diagnosed diabetic patients, identified during diabetes screening program, 1 year after diagnosis.

**Methods:** In this prospective study, 83 newly diagnosed diabetic patients identified at screening in Isfahan, were studied. Height, weight, blood pressure, plasma glucose, lipids, and hemoglobin A1c (HbA1c) of these patients were measured 2 times, first at the time of diagnosis and then 1 year later, and the results were compared between two groups, with and without regular course of treatment.

**Results:** Nearly 46.99% and 53.1% of the studied patients have regular and irregular course of treatment. After 1 year, significant improvement in the mean of plasma glucose, cholesterol, triglyceride, low density lipoprotein (LDL), high density lipoprotein and HbA1c was seen in patients with regular course of treatment except for blood pressure ( $P < 0.05$ ). Frequency of controlled cardiovascular risk factors including fasting plasma glucose, HbA1c, cholesterol and LDL was significantly improved in patients with regular course of treatment ( $P < 0.05$ ). Mentioned changes were not seen in patients with irregular course of treatment.

**Conclusions:** The findings of the current study demonstrated that though diabetes screening program result in earlier diagnosis of patients with type 2 diabetes, but it seems that regular follow-up and proper management of newly diagnosed patients is crucial for appropriate glycemic and metabolic control and preventing its related micro and macrovascular complication.

**Keywords:** Cardiovascular disease, care, screening, type 2 diabetes

### INTRODUCTION

Type 2 diabetes has emerged as a major health problem and an important cause of morbidity and mortality world-wide.<sup>[1]</sup> Epidemiological studies indicated that in spite of implementation of extensive preventive strategies the global prevalence rate of diabetes is increased significantly and it has reached to an epidemic

level.<sup>[2,3]</sup> According to the report of International Diabetes Federation diabetes currently affects 246 million people world-wide and it is estimated to reach on 380 million by 2025.<sup>[4]</sup>

The increasing rate of type 2 diabetes is alarming in developing countries mostly Middle East countries like Iran.<sup>[5]</sup> The results of a systematic review reported that the prevalence of type 2 diabetes in Iran is higher than other developing countries.<sup>[6]</sup>

Type 2 diabetes considered as an important risk factor for cardiovascular disease (CVD) with 2-4 times higher risk than the general population.<sup>[7]</sup> Coexistence of other CVD risk factors with diabetes made it as the most important condition for occurrence of CVD.<sup>[8]</sup> Numerous studies demonstrated that good glycemic and metabolic control would prevent or slow CVD in diabetic patients.<sup>[9,10]</sup>

On the other hand, recently the concept of diabetes screening and its early detection and management was developed for better management of the disease. Though the effectiveness of diabetes screening was not confirmed in all studies and there are controversial results in this field<sup>[11]</sup> but it seems that concurrent use of these two factors i.e., early diagnosis of diabetes and good glycemic and metabolic control would reduce the burden of the disease in the community. The outcome even could be more optimal by performing proper educational programmers and public awareness talks.

Evidences from different parts suggest that the majority of diabetic patients have not reached the optimal diabetes control world-wide specially by using the routine diabetes care protocols.<sup>[12,13]</sup> Thus, considering dramatic increasing rate of type 2 diabetes in our community and importance of its proper control for reducing the burden of the disease and consequently improving public health, the aim of the current study was to evaluate the quality of care and control of cardiovascular risk factors in newly diagnosed diabetic patients, identified during diabetes screening program, 1 year after diagnosis and treatment. However, the findings of the current study would be helpful in planning more effective diabetes management protocol.

## METHODS

This study performed as a part of Isfahan Diabetes Prevention Project (IDPP). In this

prospective study, first degree relatives (FDRs) of type 2 diabetic patients aged 25-55 years who diagnosed as newly diagnosed diabetic patients during this project were enrolled.

In IDPP, FDRs (Siblings and offspring) of type 2 diabetic patients aged 25-55 years were recruited to participate. Persons who had known a history of diabetes and/or were taking medications, which may affect glucose tolerance, were excluded from the study. In total, 1640 FDRs selected. Oral glucose tolerance test (OGTT) was performed in participants and according to the results of the OGTT they classified as normal, impaired fasting glucose, impaired glucose tolerance and diabetic. In this study, diabetic patients were studied. Patients with 2-h plasma glucose  $\geq 200$  mg/dl (11.1 mmol/l) during an OGTT diagnosed as diabetic patients.<sup>[14]</sup>

The Medical Ethics Committee of the Isfahan Endocrine and Metabolism Research Center approved the study protocol, and all subjects gave their written consent.

Baseline characteristics of studied population including demographics, history, clinical examination and laboratory tests representing cardiovascular risk factors (i.e., cholesterol, triglyceride [TG], high density lipoprotein-cholesterol [HDL-c], low density lipoprotein-cholesterol [LDL-c]) and glycemic control (fasting plasma glucose [FPG] and hemoglobin A1c [HbA1c]) were obtained and recorded using a questionnaire.

After diagnosis of the disease all patients recalled for initiating diabetes treatment. The protocol of diabetes management and follow-up were a standard protocol, which assessed similarly in all patients. It was based on the (American Diabetes Association [ADA]) standards of medical care in diabetes.<sup>[15]</sup>

After 1 year, all patients were recalled. They first evaluated for regular and irregular course of treatment according to their medical records during last year. Those with at least 3 times follow-up up considered as patients with regular course of treatment and those with less than 3 times follow-up up or without any follow-up up as irregular course of treatment. An internist visited and examined all patients. The laboratory tests similar to those examined at baseline were examined in all patients. The results of laboratory tests and clinical examination were recorded. The characteristics of studied population in patients

with regular and irregular course of treatment were compared at baseline and 1 year after diagnosis.

### Clinical examination

Height and weight were measured with light clothing and bare feet using a Seca scale (Seca, Hamburg, Germany) by a trained nutritionist. The weight was recorded to the nearest 100 g, and height was measured to the nearest 0.5 cm.

Body mass index (BMI) was calculated as weight divided by the square of the height ( $\text{kg}/\text{m}^2$ ).

Blood pressure was measured by a physician on the right arm in the seated position twice after at least 15 min of rest with a 5-min interval between the two measurements. The manometer was placed at the heart level.

### Laboratory examination

Participants were asked to stay on an unrestricted diet (more than 150 g of carbohydrate daily) and avoid heavy physical activity at least 3 days before laboratory tests. After an overnight fasting period of 10 h, a standard 75-g OGTT was performed. Plasma glucose and lipids (total cholesterol, HDL-c and TG) were measured by enzymatic colorimetric techniques using an auto-analyzer (Escalon, Liasys, Italy).

Inter-assay coefficients of variation were 1.25% for TG, 1.2% for cholesterol and 1.25% for glucose. The corresponding intra-assay coefficients of variation were 1.97%, 1.6% and 2.2%, respectively.

HbA1c was measured by ion exchange chromatography with a DS5 set (Drew Scientific, Dallas, Tex., USA). Inter- and intra-assay variations of HbA1c were 6.7% and 5.8%, respectively.

LDL-c was calculated using the Friedewald formula.

Undesirable levels of cardiovascular risk factors according to the ADA criteria were defined as follows; as total cholesterol  $\geq 200$  mg/dl ( $\geq 5.17$  mmol/l), TG  $\geq 150$  mg/dl ( $\geq 1.69$  mmol/l) or LDL  $\geq 100$  mg/dl ( $\geq 2.59$  mmol/l) and HDL  $< 40$  mg/dl ( $< 1.03$  mmol/l) for men and HDL  $< 50$  ( $< 1.29$  mmol/l) for women.<sup>[16]</sup>

Patients who were on antihypertensive therapy prior to study, or those whose blood pressure exceeded 130/80 mmHg were considered to be hypertensive.<sup>[16]</sup>

### Statistical analysis

Obtained data analyzed using SPSS version 18 (SPSS Inc., Chicago, IL, U.S.A.).

Normality of data distribution was assessed with Kolmogorov-Smirnov. Logtransformation was used for reducing skewness. Numeric variables were presented as mean (standard deviation [SD]). Qualitative variables have expressed as number (percent). Mean of the study variables between and within groups were compared using paired *t*-test and independent samples *t*-test. Chi-square was used for comparing the frequencies. The differences were considered as significant at  $P < 0.05$ .

## RESULTS

From studied FDRs of type 2 diabetic patients, 83 (5.06%) patients diagnosed with diabetes. Mean age of diabetic patients was  $43.4 \pm 5.6.12$  (14.5%) were male and 71 (85.5%) female respectively. From studied diabetic patients 39 (47%) were patients with regular course of treatment and 44 (53%) were patients with irregular course of treatment. Two groups of patients were similar according to sex and age.

Mean  $\pm$  SD of BMI, glycemic and lipid parameters and systolic and diastolic blood pressure at baseline and 1 year after diagnosis of diabetes in patients with regular and irregular course of treatment are shown in Table 1.

At baseline all studied variables were not different significantly in two studied patients with and without regular population ( $P > 0.05$ ).

One year after follow-up up BMI, FPG, HbA1c, total cholesterol, TG, LDL-c and diastolic blood pressure decreased significantly in diabetic patients with regular follow-up up ( $P < 0.05$ ). HDL-c increased significantly in diabetic patients with regular follow-up up ( $P < 0.05$ ). Systolic blood pressure had not significant change ( $P > 0.05$ ).

One year after follow-up up HDL-c and diastolic blood pressure increased significantly in diabetic patients without regular follow-up up ( $P < 0.05$ ). BMI decreased significantly in diabetic patients without regular follow-up up ( $P < 0.05$ ).

One year after follow-up mean differences of FPG, HbA1c, TG and LDL-c was significantly higher in diabetic patients with regular follow-up up than those without regular follow-up up ( $P < 0.05$ ).

Frequency of controlled risk factors in all newly diagnosed type 2 diabetes patients is presented in Figure 1.

Frequency of controlled risk factors in newly diagnosed type 2 diabetes patients with regular

**Table 1:** Mean±SD of BMI, glycemic and lipid parameters and systolic and diastolic blood pressure at baseline and 1 year after diagnosis of diabetes in patients with regular and irregular course of treatment

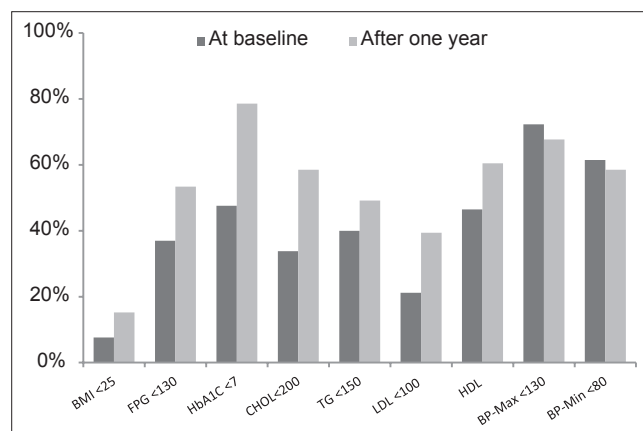
Characteristic	Regular follow-up up group n=39			Irregular follow-up up group n=39		
	Baseline	After 1 year	Mean difference	Baseline	After 1 year	Mean difference
BMI (kg/m <sup>2</sup> )	29/78±4/03	28/85±4/03	0.93±1.85	30/19±4/17	29/23±4/48	0.96±1/57
FPG (mg/dl)	169/08±63/81	129/18±32/76	39.89±64.35	157/14±75/97	150/9±53/52	7/06±57/14
HbA1c (%)	7/37±2/43	6/21±1/72	1.15±2.18	7/56±2/15	7/04±2/17	0/48±1
Total cholesterol (mg/dl)	219/36±49/27	195/67±41/75	23.69±47.1	215/28±44/44	202/17±36/42	13/1±51/15
Triglyceride (mg/dl)	213/47±159/94	151/64±85/27	61.83±112.1	198/72±86/32	179/34±64	19/38±74/89
LDL-cholesterol (mg/dl)	128/15±29/1	103±25/74	25.15±30.18	123/08±28/77	115/08±27/35	8±21/9
HDL-cholesterol (mg/dl)	47/75±10/33	52/67±10/78	-4.91±11.37	41/11±13/89	48/79±12/35	-7/68±12/38*
Systolic blood pressure (mmHg)	124/85±14/06	125/59±18/78	-0.74±16.24	127/42±19/01	132/1±25/16	-4/67±19/91
Diastolic blood pressure (mmHg)	78/38±11/4	73/38±13/18	-5.0±13.54	78/87±13/77	84/52±13/62	-5/65±12/83*

\* $P < 0.05$  between baseline and 1 year after follow-up for BMI, HDL and diastolic blood pressure in regular follow-up group.

\* $P < 0.05$  between baseline and 1 year after follow-up for all variables except systolic blood pressure in regular follow-up group. \*\* $P < 0.05$  after 1 year follow-up between regular and irregular follow-up groups for FPG, HbA1c and triglyceride.

£ $P < 0.05$  mean differences between regular and irregular follow-up group for FPG, HbA1c, triglyceride and LDL-cholesterol.

SD=Standard deviation, BMI=Body mass index, FPG=Fasting plasma glucose, HbA1c=Hemoglobin A1c, LDL=Low density lipoprotein, HDL=High density lipoprotein

**Figure 1:** Frequency of controlled cardiovascular risk factors in all newly diagnosed type 2 diabetes patients.

\* $P < 0.05$  for fasting blood glucose, hemoglobin A1c and cholesterol

and irregular course of treatment are presented in Figure 2.

## DISCUSSION

In this study, we evaluate the quality of care and frequency of diabetes related cardiovascular risk factor in newly diagnosed diabetic patients, identified during diabetes screening program, with regular and irregular course of treatment. The findings of the current study indicated that only half of the diagnosed patients had proper

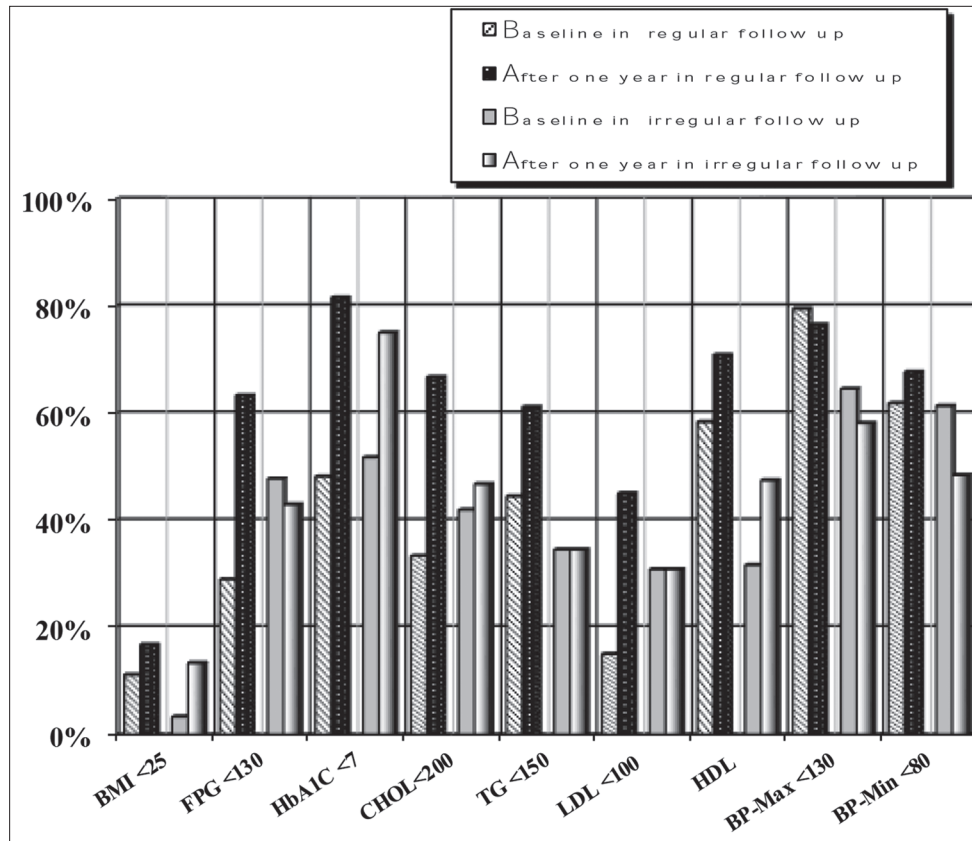
and regular course of treatment according to our research center protocol. Another achievement of the current study was that the control of cardiovascular risk factors in patients with regular course of treatment was more appropriate than those with irregular course of treatment.

Many studies from both developed and developing country indicated that in most of the diabetic patients the quality of diabetes care were below the standard recommendations and they had not achieved their appropriate glycemic control as well.<sup>[12,13]</sup>

Azam *et al.* in Pakistan have evaluated the quality of type 2 diabetes care indifferent clinics in Karachi and indicated that a high proportion of studied diabetic patients had not received proper diabetes care.<sup>[17]</sup>

In this study, mean of FPG, HbA1c, cholesterol, TG and LDL decreased significantly after assessment of 1 year regular course of treatment. Frequency of controlled risk factors including FPG, HbA1c, cholesterol and LDL in this group of patients increased significantly after mentioned period of regular treatment and follow-up up. The findings indicated that the treatment was effective enough for decreasing the level of FPG, HbA1c, cholesterol and LDL. However regarding other risk factors such as weight, TG and HDL the reduction rate was not significant. One year





**Figure 2:** Frequency of controlled cardiovascular risk factors in newly diagnosed type 2 diabetes patients with regular and irregular course of treatment. \*P < 0.05 for fasting blood glucose, hemoglobin A1c, cholesterol and low density lipoprotein

follow-up in patients with irregular course of treatment indicated that mentioned risk factors were not changed significantly.

O'Connor *et al.* in the USA evaluated the changes in glycemic control and cardiovascular risk factors in newly diagnosed diabetic patients 1 year after its diagnosis. They showed that after 12 months all patient subgroups had significant improvement in glycemic control (HbA1c; from 8.8% to 7.1%) and cardiovascular risk factors including systolic and diastolic blood pressure and weight.<sup>[18]</sup>

In our study, systolic and diastolic blood pressure in both patients with regular and irregular course of treatment was not changed significantly. The frequency of controlled blood pressure in both groups was not increased significantly, too.

Reviewing the medical files of the diabetic patients indicated that only 30.6% of our hypertensive diabetic patients were on antihypertensive treatment and mostly with one drug. Most of the diabetic hypertensive patients did not received any treatment in this regard. Hence, it seems that the unsatisfactory management of blood pressure in this group of

diabetic patients may be due to inappropriate management of hypertension in this high risk population. However studies indicated that blood pressure is one of the most important risk factors of CVD in this group of patients and optimal control of hypertension could significantly result in reduced CVD and its related mortality.<sup>[19,20]</sup>

The results of this study were in accordance with that reported by Edelman *et al.* in the USA. Likewise our study, they follow-up up 53 diabetic patients diagnosed by systematic screening and indicated that the proportion of patients with systolic blood pressure of >140/90 was similar at baseline and 1 year after diabetic care and follow-up. They concluded that in order to improve the management of hypertension in diabetic patients and consequently reduce the CVD and its related morbidity and mortality, diabetes screening program should be coupled with other effective interventions.<sup>[21]</sup>

Recently, several studies reported that diabetes management needs a multidisciplinary approach for better glycemic control and preventing its

related complication and morbidity and mortality and routine diabetes management protocols, used routinely in diabetes clinics, do not work properly.<sup>[22]</sup> In addition, some of them demonstrated that early intensive multifactorial treatment in newly diagnosed patients with diabetes during its screening program not only is more effective in better glycemic control, but also in a significant reduction of its related cardiovascular events and mortality.<sup>[23,24]</sup>

In this study, our results indicated that routine standard care which is used in our center was appropriate enough for achieving proper goal in diabetes control and management during diabetes screening program in Isfahan. Similar results reported by O'Connor *et al.* also.<sup>[18]</sup>

Though routine diabetes management and regular follow-up among newly diagnosed type 2 diabetes patients, identified during screening, result in better glycemic control and CVD risk factors control except for blood pressure, but it seems that optimal preventive goals would be achieved through more intensive diabetes management and multifactorial approaches. It is recommended to design further studies for evaluating the effectiveness of intensive versus routine diabetes management protocol in quality of care of newly diagnosed type 2 diabetes.

Considering the outcomes of the current study especially inappropriate blood pressure control in diabetic patient, it seems that physicians involved in the management of diabetes in our center did not consider diabetes as a metabolic disorder which needs both pharmacological and behavioral interventions. Hence, it is recommended to consider educational approaches in diabetes management including self-management, lifestyle modification and weight control during follow-up up periods of diabetic patients.

The limitation of our study was that blood pressure was measured only 1 time during 1 year follow-up up period. Similarly other CVD risk factors including fasting blood sugar, lipid profile and HbA1c was measured only in one follow-up up period. It seems that mean of mentioned risk factors obtained from multiple measurements would be more helpful and conclusive. Regularity of the follow-up up was determined by reviewing the patients profile from diabetes diagnosis. But because the period of the study was not long enough the measurement was done only once.

## CONCLUSIONS

The findings of the current study demonstrated that though diabetes screening program result in earlier diagnosis of patients with type 2 diabetes but it cannot be effective enough for appropriate glycemic and metabolic control and preventing its related micro and macrovascular complication and also cost effectiveness if newly diagnosed patients not received proper and regular management from the time of diagnosis.

Moreover, though both patients and physicians are responsible for the outcome of the disease management but it seems that more studies should be designed to determine the barriers of effective treatment and managements of the disease. However identification of these barriers and their contribution could help us in providing proper management protocol for diabetes care and achieving better preventative strategies.

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