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## Original Article

# The ABC of diabetes. How many patients are able to achieve the goal laid down by American Diabetes Association?

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## ABSTRACT

**Background:** To study the number of patients with Type 2 Diabetes Mellitus who achieve the glycemic, blood pressure and LDL-Cholesterol targets as per American Diabetes Association, Standard of Care for Management of Diabetes.

**Methods:** Hundred patients of Type 2 Diabetes mellitus were recruited from December 2008 to January 2009 from an Endocrinology OPD of tertiary care hospital and followed up for six months. Glycosylated hemoglobin (HbA1c), blood pressure (BP) and LDL-Cholesterol (LDL) were estimated at baseline and prevalence of those at target (HbA1c <7%, BP < 130/80 mm Hg, LDL < 100 mg/dl) was documented and repeated at three and six months to monitor improvement in the number of patients at target and trend in improvement of individual parameters.

**Results:** The percentage of patients at target at baseline and six months for HbA1c was (45% vs. 55%  $p = 0.101$ ), BP < 130/80 mm Hg (27% vs. 25%) and LDL < 100 mg/dl (37% vs. 40%  $p = 0.386$ ). All three parameters were at target in one patient and three patients at six months period. Mean values at baseline and six months of HbA1c 7.46% (95% CI 7.17–7.75) vs 7.21% (95% CI 6.9–7.52), Systolic BP 138 mm Hg (95% CI 135–141), Diastolic BP 86 mm Hg (95% CI 84–86) and LDL 114 mg/dl (95%CI 107–121) vs. 110 mg/dl (95%CI 105–116) did not show significant improvement ( $p$  for trend).

**Conclusion:** Standards of care for HbA1c, blood pressure and LDL remains to be achieved in majority of the diabetic patients.

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## Introduction

Diabetes mellitus (DM) is a chronic and progressive disease that is growing rapidly in prevalence. It has been estimated by the year 2030 there would be approximately eighty seven million patients with diabetes in India.<sup>1</sup> The long term

complications associated with diabetes are major cause of morbidity and mortality, imposing a high financial burden on health care system.<sup>2</sup> The management of patients with diabetes does not limit to control of blood glucose; it also includes control of other factors like blood pressure and dyslipidemia. Professional bodies like the American Diabetes Association (ADA) have issued guidelines regarding Standards of Medical

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Care for management of diabetes.<sup>3</sup> These guidelines have been formulated based on evidence from clinical trials which have shown consistent decrease in morbidity and mortality due to diabetes by multifactorial intervention. However achievements of the goals set for optimum management as per guidelines is far from satisfactory. In a retrospective study to assess quality and effectiveness of diabetes care for a group of patients in Colombia it was shown that only 6.9% of patients had achieved the goals recommended for control of glucose, lipids and blood pressure.<sup>4</sup> However such surveys are lacking in India and we do not have data regarding achievement of ADA recommendations in Indian setting.

## Materials and methods

We undertook this study to estimate the number of patients with Type 2 Diabetes Mellitus who achieved the goals laid down by ADA (Glycosylated Hemoglobin (HbA1c) < 7%, blood pressure (BP) < 130/80 mm Hg, Low Density Lipoprotein (LDL) < 100 mg/dl over follow up period of six months. Hundred patients fulfilling diagnostic criteria of Diabetes Mellitus as per ADA guidelines and attending endocrinology OPD of a tertiary care hospital were recruited after informed consent. Detailed history regarding duration of diabetes, medicines taken, complications (microvascular and macrovascular) was taken. Patients above 70 years of age, patients with macroalbuminuria or end stage renal disease, severe non-proliferative diabetic or proliferative retinopathy, co morbidities like ischemic heart disease, congestive cardiac failure and malignancy were excluded. The patients were followed up monthly with blood pressure recordings and estimation of blood glucose. The treatment modifications were done to achieve parameters of ABC (HbA1c, BP and LDL-Cholesterol) as per ADA guidelines. Education on diabetes control was provided during OPD visits. All patients were referred to a dietician for counseling about diet. Levels of HbA1C and serum lipids were estimated at baseline, three and six months. HbA1C was estimated by HPLC, and lipids were assessed by enzymatic methods. The data was analyzed with the statistical program SPSS 15.0 for Windows. The change in parametric variables between baseline, 3 months and 6 months were analyzed by paired t-test. Dichotomous variables were created from parametric variables like HbA1c, LDL, systolic (SBP) and diastolic blood pressure (DBP) recordings. They were analyzed by chi-square test. Statistical significance was set at  $p < 0.05$ . The parametric variable were analyzed by generalized linear model ( $p$  for trend) to assess change in group variables.

## Results

A total of 100 patients of type 2 diabetes mellitus were recruited based on the inclusion criteria. In the present study, male subjects comprised of 48 and female subjects of 52 respectively. The mean age of the patient was  $59 \pm 10.5$  years (38–90) and mean BMI was  $25.17 \pm 3.65$  kg/m<sup>2</sup> (range 15.14–36.69). The prevalence of patients with the HbA1c, LDL and BP at baseline, 3 and 6 months is shown in Table 1. HbA1c was at target in 45% at baseline. However no significant change occurred in number

of patients at three and six months ( $p = 0.101$ ). Less than 30% of patients had blood pressure at target values at baseline and no appreciable change was noticed in numbers at follow-up visits. LDL-C was at target (<100 mg/dl) in 37% at baseline and 40% at six months ( $p = 0.386$ ). It was observed that only one patient had achieved all the recommended parameters of optimum care as per ADA guidelines. At six month follow up three patients (3%) achieved the recommended targets for adequate glycemic control. A generalized linear model was used to analyse the trend in improvement in values of various parameters (HbA1c, SBP, DBP and LDL) over period of six months. No significant trend ( $p$  for trend) was observed for improvement in the above parameters of metabolic control over the six month period. (Table 2)

## Discussion

This study was meant to assess the prevalence of patients with diabetes who met the criteria for ABC as per Standard of Care laid down by ADA and follow them over a period of six months with treatment modification as per guidelines. Parameters to be studied were recorded at baseline, three and six months and there were no dropouts. The results suggest that less than fifty percent patient had attained desired values of HbA1C at baseline with no significant improvement in the prevalence at six months. Observational studies in health care setting around the globe have shown similar results with poor glycemic control. EPIDIAP study in Spain in 2007 was a cross-sectional epidemiological study of clinical profiles and glycemic control in diabetic patients. A total of 679 patients were included Type 1 DM (11.5%), insulin-treated Type 2 DM (26.2%) and noninsulin-treated Type 2 DM (62.3%). Only 53.1% had achieved target HbA1c values (distribution among groups: 31.5%, 32.7% and 65.4%, respectively;  $p < 0.001$ ).<sup>5</sup> A cross-sectional study of outpatients with Type 2 diabetes mellitus in tertiary hospitals in the Jiangsu province of China in 2009 showed that 43.9% of patients had achieved desired values of HbA1c.<sup>6</sup> In Diab-Care Asia multi-country study in Asia, 50% had poor control as measured by HbA1c.<sup>7</sup> A trend for poor control of blood pressure and serum LDL-C in diabetic patients has also been observed in several observational studies worldwide. A retrospective study to assess the quality of Diabetes care in U.S. Academic medical centers revealed that despite high annual testing rates only 34% patients had HbA1c < 7%, 33% had blood pressure less than 130/80 mm Hg and 46.1% had LDL cholesterol levels below 100 mg/dl. Only 10% of cohort met recommended goals for all three risk factors.<sup>8</sup> The Look AHEAD study found in a cohort of 5145 diabetic patients only 10.1% met the criteria of control for all three parameters.<sup>9</sup> A similar study in Colombia found that only 6.9% had achieved

**Table 1 – Percentage of patients at target as per ADA guidelines.**

	Baseline	Three months	Six months
HbA1c < 7%	45	53	55
BP < 130/80 mm Hg	27	23	25
LDL-C < 100 mg/dl	37	33	40

**Table 2 – Generalized Linear Model for evaluation of parameters (mean values) achieved at 3 & 6 months.**

Parameter	0 month (95% CI)	3 months (95% CI)	6 months (95% CI)	P for trend
HbA1c	7.46 (7.17–7.75)	7.21 (6.94–7.48) ( $p < 0.0001^*$ )	7.21 (6.9–7.52) ( $p < 0.001^{**}$ )	0.396
SBP (mm Hg)	138 (135–141)	136 (133–139) ( $p < 0.026^*$ )	134 (132–136) ( $p < 0.001^{**}$ )	0.108
DBP (mm Hg)	86 (84–88)	85 (84–86) ( $p < 0.231^*$ )	84 (83–85) ( $p < 0.022^{**}$ )	0.406
LDL-C (mg/dl)	114 (107–121)	113 (107–119) ( $p < 0.757^*$ )	110 (104–116) ( $p < 0.123^{**}$ )	0.749

\*paired t-test for 0 & 3 months, \*\*paired t-test 0 & 6 months

recommended levels for all three parameters.<sup>4</sup> In recently published data from a nationwide survey in United States during the period 2007–2010 out of a cohort of 4296 adults  $\geq 20$  years with diabetes, 52.5% of patient had HbA1c  $< 7\%$ , 51% had BP  $< 130/80$  mm Hg, 56.2% achieved LDL  $< 100$  mg/dl and 18.8% achieved all three parameters.<sup>10</sup>

### Trend analysis

A trend to improvement of various parameters was not observed in our study. Various factors need consideration while analyzing trends in epidemiological studies. These include sample size, presence of outliers and time period of observation.

Failure to achieve ABC targets could be related to patient, physician and systemic factors. Quality of diabetes care is dependent on interaction between the above three factors. e.g., the primary responsibility of a patient in diabetes care is adherence to life style measures and anti diabetic medications which is dependent on a healthy interaction between the health care provider and the patient. Systemic factors interact with patient in the form of providing accessibility and availability of medicines. Systemic factors interact with physician factors including administrative, time pressures and educational barriers.<sup>11</sup> Our study can be considered a pilot study due to small sample size and study of trends in health care can be inferred after longer period of observation. The strength of our study was we attempted first of a kind audit of diabetes care in a service hospital. We had ensured a hundred percent follow up of patients for six months. The limitations of our studies were that it was a single center study with limited number of patients and short duration of follow-up.

The increasing prevalence of Type 2 Diabetes Mellitus is likely to increase the morbidity associated with diabetes and has serious implications in terms of health care costs.<sup>1,2</sup> The results of our study should be viewed from the context of requirement of multiple agencies in managing a chronic disease like diabetes. We feel that management of diabetes can be strengthened by adopting a chronic disease model which starts with community based awareness program, periodic screening of diabetes in high risk individuals, improving patient education by providing diabetes educators and nutritionist at designated clinics, ensuring availability of drugs and periodically reviewing and benchmarking the quality of care of diabetic patients in Armed Forces.

### Conflicts of interest

All authors have none to declare.

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