

## Current understanding of treatment and management protocol for adult diabetic in-patients at a tertiary care hospital

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### Abstract

**Objective:** To assess the current understanding of treatment and management protocols for adult diabetic in-patients at a tertiary care hospital.

**Methods:** This cross-sectional study, conducted at the Civil Hospital Karachi from July to September 2009, involved 450 participants, who were interviewed through a well-structured questionnaire regarding the patient's demography, clinical features, past medical history, type of diabetes mellitus, duration, associated complications, and also involved patient notes for laboratory tests and management. SPSSv15.0 was used for descriptive analysis.

**Results:** The study population of 450 diabetics had 144 (32%) males and 306 (68%) females. Of the total, 435 (96.7%) patients had type 2 diabetes. There were 231 (51%) patients using insulin, 168 (37.3%) oral hypoglycaemic drugs, and 51 (11.3%) using both. Among patients using insulin, regular insulin usage stood at 30% followed by a combination of regular insulin and NPH (26.7%) and NPH alone at 6%. The most popular drug used was metformin (27.3%) and the least used drug was glitazones (4%). In the study population, 73.3% patients controlled their diabetes with diet, and 24.7% with regular exercise.

**Conclusion:** Majority of the study population had type 2 diabetes with a female preponderance. Insulin was prescribed for half the patients. Metformin was the most frequently used oral hypoglycaemic drug.

**Keywords:** Diabetes mellitus, Treatment protocols, Insulin, Oral hypoglycemic agent (JPMA 62:520; 2012).

## Introduction

Diabetes is a chronic and potentially disabling disease. It poses a huge burden on the world's health status today and it is vital that the disease process is recognised and evaluated promptly. With persistent disturbances of carbohydrate, fat and protein metabolism, diabetes becomes a progressive disease, causing complications in the long term such as retinopathy, nephropathy and neuropathy.<sup>1</sup> Macrovascular (cardiovascular disease and stroke) and microvascular complications account for approximately 65% of all mortality in the affected people aged 20-74 years.<sup>2</sup> Correct and timely identification and diagnosis is essential to the accurate management and treatment of diabetes, most complications of which can be controlled if treatment is started at an initial stage.

Type-2 diabetes is the more common of the two main types (type 1 and 2) and accounts for between 85-95% of all diabetic patients.<sup>3</sup> According to the World Health Organization (WHO), the number of total diabetic patients worldwide in the year 2000 were 171,000,000 which will skyrocket to 366,000,000 by year 2030.<sup>4</sup> In Pakistan, the prevalence of diabetes in the age group 20-79 years is 6.2 million which reflects that over 11% of the adult population is suffering from DM in the country. Moreover, a similar proportion of the population in Pakistan has impaired glucose tolerance (IGT) which is expected to rise more rapidly in future.<sup>5</sup>

Current diabetes guidelines recommend that patients maintain glycosylated haemoglobin levels (HbA1C) of less than 7%, a blood pressure of below 130/80 mm Hg, and an LDL of less than 100 mg/dl in order to minimise the risk of developing microvascular and macrovascular complications.<sup>6</sup> The achievement and maintenance of these goals often requires lifestyle modification and an increasing number of medications over the duration of a patient's disease. The pursuit of these goals has come to define modern comprehensive diabetes care.<sup>6</sup> Conventional treatment of diabetes focuses on insulin for type 1 (insulin-dependent) patients and oral agents for type 2 (non-insulin-dependent) patients, in addition to dietary and lifestyle changes. The oral hypoglycaemic agents include metformin, sulphonylureas, meglitinides, glucosidase inhibitors and thiazolidinedione,<sup>3</sup> di-peptidyl peptidase 4 inhibitors and incretins.

Although much work has been done to evaluate the most appropriate management and treatment techniques for diabetes, it is limited to the western countries. There is a dearth of such audits in Pakistan which is regrettable given the significant incidence of diabetes in the country. This study aimed at critically analysing contemporary practices in the management and treatment of diabetes type 1 and 2 in our public health setup, and highlighting the changes in the previous trends, if any.

## Materials and Methods

This cross-sectional study was conducted in Civil

Hospital Karachi, a tertiary care hospital with 1800 beds catering to over 1000 patients on a daily basis. Patients are generally from lower socio-economic background of the city and those referred from other centres.

The study was conducted between July 1 to September 30, 2009, on admitted patients aged 16 years and above in different wards which included Medicine, Gynaecology and Obstetrics, General Surgery, Orthopaedic Surgery, Cardiac Surgery, Ophthalmology and Otorhinolaryngology. Inclusion criteria comprised patients who had reports of basic diabetic investigations, urine analysis, and blood reports carried out within the study year. Paediatric and out-patient populations were excluded, the reasons being our coverage of type 2 diabetes, massive patient-load, and the lack of relevant lab results. The sampling technique used was non-probability purposive sampling. The sample size was not calculated earlier. There were 512 patients who met the inclusion criteria, but only 450 consented to participate in the study. All these subjects had diabetes mellitus as the primary complaint or as an existing co-morbidity.

Data were collected on pre-designed, structured questionnaires. Informed consent was taken from the patients before the interview. The first section consisted of patient's demography, including age, gender and family history of diabetes. The second portion consisted of a medical overview of the patients existing co-morbid conditions and complications like hypertension, nephropathy and type of DM, duration, associated complications and laboratory tests like Fasting Blood Sugar, Random Blood Sugar, Serum Creatinine and Urine Albumin. Finally, management was discussed which included both therapeutic and non-therapeutic measures. The data was processed on Statistical Package for Social Sciences (SPSS version 16) for statistical analysis. Frequencies and percentages were computed for descriptive analysis as all variables were qualitative in nature. The ethical approval for the study was obtained from the Ethical Review Board (ERB) of the Dow University of Health Sciences (DUHS).

## Results

A total of 450 patients with diabetes mellitus either as a primary complaint or as a co-morbid were registered. There were 144 (32%) males and 306 (68%) females. A total of 15 (3.3%) patients had type-1 diabetes and 435 (96.7%) had type-2 diabetes. Family history was positive in 192 (42.7%) patients. There were 123 (27.3%) patients who were less than 40 years, 246 (54.7%) were between the ages of 41 and 60, and 81 (18%) were above 60 years [range 16-85 years]. A total of 144 (32%) patients had diabetes for less than 2 years, 225 (50%) had it for between 2 to 10 years, and 81 (18%) had it diagnosed for more than 10 years. There were 192 (42.7%) patients who had retinopathy, 132 (29.3%) had neuropathy either peripheral or autonomic, 150 (33.3%) had nephropathy, while 294 (65.3%) patients had trace amounts of urine albumin, 12 (2.7%) had

raised serum creatinine, and 96 (21.3%) had diabetic foot on assessment.

Hypertension was found in 240 (53.3%), 135 (30%) had a history of CAD whereas 177 (39.3%) had hypoglycemic episodes. Further, 324 (72%) had fasting blood sugar (FBS) values greater than 125 mg/dl, 81 (18%) had less than 110mg/dl, and 45 (10%) had impaired fasting blood glucose i.e. between 110-125 mg/dl. When checked for random blood sugar (RBS), 330 (73.3%) had values above 199 mg/dl, 15 (3.3%) had below 140 mg/dl, and 105 (23.3%) were under high risk for diabetes.

Insulin Therapy - either alone or in conjunction with OHAs — had been decided for 282 (62.7%) patients by their respective physicians, in which 135 (30%) patients were prescribed regular insulin, 27 (6%) NPH, while 120 (26.7%) were prescribed both regular insulin and NPH.

A total of 219 (48.7%) patients who used oral hypoglycaemics were satisfied with their medications. Out of these, 18 (4%) used glitazones, 123 (27.3%) metformin, 39 (8.7%) sulfonylurea alone, while 18 (4%) used both metformin and glitazones, and 21 (4.7%) used both sulfonylurea and metformin.

Insulin alone was prescribed for 231 (51.3%) patients, 168 (37.3%) used oral hypoglycaemics alone, while 51 (11.3%) used insulin and oral hypoglycaemics simultaneously.

There were 330 (73.3%) patients who used a controlled diet, 96 (21.3%) did regular self-monitoring of both blood sugar

levels and blood pressure. Regular exercise was done by 111 (24.7%) patients; 237 (52.7%) reduced their weight after the diagnosis of diabetes; and 75 (16.7%) patients were smokers (Figure).

## Discussion

To manage diabetes it is important to prevent its grave consequences. The treatment includes medications and lifestyle modifications for better prognosis. A study showed that more than half of the patients were recommended diet control and exercise by healthcare professionals to prevent disease progression.<sup>7</sup>

Although published literature shows that diabetes affects both the genders equally, but recent studies have showed female dominance, especially in developed countries.<sup>8</sup> Our results also showed 68% women and 32% men.

The age range found most susceptible in our study was 41-60 years which, again, is comparable with international literature that showed 45-64 years in the developing countries.<sup>8</sup> Family history of diabetes is a significant predictor of diabetes prevalence in the adult population.<sup>9</sup> We concluded the same on the basis of our findings, with 42.7% having a family history. Our results also showed that 96.7% of the study population had type 2 diabetes with only 3.3% having type-1. This is a purely incidental finding.

Diabetes does not always occur as the only disease. It is commonly associated with co-morbidities such as hypertension and heart disease. It also increases the risk for conditions that predispose individuals to hospitalisation like coronary artery disease, cerebrovascular and peripheral vascular disease, infection, nephropathy and lower-limb amputations.<sup>10</sup> Progressive disease can lead to both microvascular and macrovascular complications,<sup>2</sup> the latter accounting for approximately 65% of all the mortality in diabetics.

International statistics show that there is a 3:1 ratio with prevalence of hypertension being 42.8% in diabetic patients as compared to the non-diabetics.<sup>11</sup> More than half of our patients, 53.3%, had hypertension as an existing co-morbid along with diabetes. Our criteria for labeling patients as hypertensive included a positive history and physical examination, including blood pressure recordings. The cut-off values for blood pressure were 140/90.<sup>12</sup>

DM also increases the risk for atherosclerotic vascular disease, which is most common in people with dyslipidaemia, hypertension, smoking and obesity.<sup>13</sup> International studies show a CAD prevalence of 28.8 per 1000 male diabetic patients as compared to 23.3 per 1000 female diabetics.<sup>14</sup> Our study showed a 30% prevalence of CAD and our basis of diagnosis was a positive history for angina or myocardial infarction.

One of the major microvascular complications, making

**Table: Co-Morbidities.**

	Frequency n (%)
Hypertension	240 (53.3)
Coronary Artery disease	135 (30)
Retinopathy	192 (42.7)
Neuropathy	132 (29.3)
Diabetic foot	96 (21.3)
Nephropathy	138 (33.3)

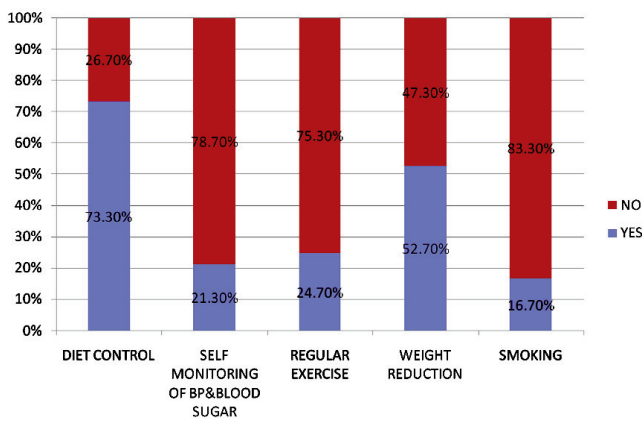


Figure: Non-Therapeutic Measures.

diabetes the leading cause of new cases of blindness in the adult population,<sup>2</sup> is retinopathy. Worldwide statistics show that about 64% of insulin treated diabetics have retinopathy as compared to 36% of OHA users, while diabetics following only diet and lifestyle modification show 12% prevalence with no age or gender predilection.<sup>14</sup> Our study showed a 42.7% prevalence of retinopathy in the patients studied and our basis for positive labeling of retinopathy was the reports of fundoscopic examinations.

In developed countries, diabetic nephropathy is one of the most common causes of end-stage renal failure.<sup>12</sup> International data show 40% of diabetic patients have nephropathy.<sup>15</sup> Our results showed 33.3% of the diabetics suffering from nephropathy. Our basis of diagnosis relied upon urine microalbumin and serum creatinine levels found in the patients records.

Neuropathy is a common early complication affecting nearly 30% of diabetics.<sup>12</sup> Its prevalence is related to the duration of disease and the degree of metabolic control. Our basis of diagnosis was subjective, depending upon the patient's positive response to paraesthesia, numbness and burning sensation in the soles of their feet. Hence, we found a prevalence of 29.3%.

Diabetic foot, in our setup, is a common reason for hospitalisation and sometimes amputation is the only option available. Approximately 15% of the world diabetics suffer from complications of foot ulceration due to neuropathy and peripheral vascular disease.<sup>16</sup> Our study showed a 21.3% prevalence of diabetic foot due to improper foot care.

The diagnosis for diabetes is primarily made on history and laboratory results which also play an important role in determining the mode of treatment. The normal range for creatinine is 0.6-1.2 mg/dl.<sup>12</sup> Approximately 90.7% of our subjects had elevated levels. In the United States, diabetic women are encouraged to maintain a mean serum creatinine value of 0.96 mg/dL.<sup>17</sup>

A urinary albumin level of  $\geq 0.03\text{mg/l}$ <sup>18</sup> is marked as the cut-off range for diabetic nephropathy. Amongst our subjects, 34.7% had trace albumin in their urine samples.

The ranges for FBS include normal  $< 100$  mg/dl, impaired glucose tolerance between 100-125 mg/dl and diabetic  $> 125$  mg/dl. RBS  $< 140\text{mg/dl}$  is normal, 140-199 mg/dl falls under the IGT category and  $> 199$  mg/dl is labeled diabetic.<sup>12</sup> In our study, 72% of population had FBS levels greater than 125mg/dl, and 73.3% had RBS levels greater than 199 mg/dl.

The focus of our study was to evaluate physician prescription and patient utilisation patterns associated with oral pharmacological management of diabetes. The data clearly confirmed that the disparity associated with pharmacological management of this chronic disease is dependent on patient compliance and persistence as well as on factors like physician's

preference and costs.

The usage pattern of insulin, as shown in our study, is also a significant factor.

Amongst the 62.7% patients using insulin — either alone or with an OHA Regular insulin usage was 30% followed by a combination of Regular insulin and NPH (26.7%), and NPH alone at 6%. This reflects the popular and commonly prescribed usage of regular short-acting insulin and a combination of short and intermediate acting insulin. Ultra-short acting insulin (lispro, aspart and glulisine) were unavailable in our study setting for economic reasons.

Among the 48.7% OHA users, including those who were on insulin as well, the most common (27.3%) was the use of metformin alone, followed by sulfonylurea alone (8.7%), combination of sulfonylurea urea and metformin (4.7%), and the least used was a combination of glitazone plus metformin and glitazones alone at 4% each. This reflects commonly prescribed drug preferences, as biguanides (metformin) and sulfonylureas are the treatment of choice for type 2 diabetes treatment.<sup>19</sup>

After an extensive literature search, we were unable to find the individual prevalence of various drugs or types of insulin recorded for a significant population. Thus, we believe that we have conducted a novel research by assessing the usage with exact values of the multiple medicinal therapies prescribed in a tertiary care hospital setting.

According to our data, 73.3% of the patients controlled their diet after being diagnosed with diabetes. Besides, 21.3% self-monitored their blood sugar levels once a week. This is low in comparison with an international study which had 39 % of the patients self-monitoring their sugar levels at least once a day.<sup>20</sup> Regular exercise, an important modality, was done only by 24.7% of the patients, mostly due to lack of awareness about its importance and a non-serious attitude about its benefits. Among the study populations 16.7% were smokers, compared to 27.3% of the US diabetic population.<sup>21</sup> Our results also showed that 20.7 % of the patients had cut down on their smoking.

In terms of limitations, our research had a modest sample size due to the fact that during the fasting month of Ramadan, the patient load is relatively less. Also, a number of laboratory-related parameters, like HbA1c, were included initially, but had to be excluded due to the lack of records and inefficient file management. Hence, fasting and random blood sugar levels were used to support the diagnosis.

## Conclusion

The study on indoor patients of Civil Hospital, Karachi showed an expected majority of type 2 diabetes with female preponderance. Half of the patients were on insulin therapy. Metformin was the most frequently prescribed oral drug and only a small percentage performed exercise.

This observational study has provided a baseline for making improvements in management of patients with diabetes.

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