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THE PREVALENCE OF DIABETES MELLITUS ITS CURRENT TREATMENT TRENDS

AMIT VAIBHAV*, O. P. SINGH** AND ANIL KUMAR TRIPATHI***

Declaration

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Abstract

Diabetes Mellitus is a set of metabolic diseases in which the body cannot regulate the amount of sugar level in the blood due to some reasons. The level of sugar especially glucose increases more than appropriate limit in blood that causes several complexities and triggers several diseases, even death. It is one of the most common endocrine disorders affecting almost 6% of the world's population. It is a group of disease characterized by elevated blood glucose concentration because of diminished or exhausted insulin secretion from pancreatic β -cells and insulin resistance. Diabetes is a leading cause of blindness, renal failure, nerve damage which can lead to erectile dysfunction (impotence), foot and leg amputations in adults. The prevalence of diabetes mellitus (DM) is increasing rapidly in the 21st century as a result of obesity, an ageing population, lack of exercise, and increased migration of susceptible patients. Type 2 DM is the more common form and the primary aim of management is to delay the micro- and macrovascular complications by achieving good glycaemic control. This involves changes in lifestyle, such as weight loss and exercise, and drug therapy In this present study an effort is made to give a concise view about diabetes in present global scenario along with its treatment possibilities.

Keywords: Diabetic mellitus, hyperglycemia, blood glucose, pancreatic beta cell, global scenario.

Introduction

Diabetes has emerged as a major health care problem globally and is one of the top five leading causes of death in most developed countries. A substantial body of evidence suggests that it could reach epidemic proportions particularly in developing and newly industrialized countries. It has been estimated that the global burden of type 2 diabetes mellitus (T2DM) for 2010 would be 285million people (2010) which

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is projected to increase to 438 million in 2030; a 65 % increase. Similarly, for India this increase is estimated to be 58%, from 51 million people in 2010 to 87 million in 2030¹ Indeed, by the year 2025, three-quarters of the world's 300 million adults with diabetes will be in developing countries and almost a third in India and China alone². The global diabetes numbers are out, and it's not looking too good for India. The prevalence of diabetes in India is showing a sharp upswing as is evident from secular trends from different parts of the subcontinent and studies of migrant Indians.³ The World Health Organization has estimated that in 1995, 19.4 million individuals were affected by diabetes in India and these numbers are expected to increase to 57.2 million by the year 2025 i.e. one- sixth of the world total.¹ The revised figures are 80.9 million by the year 2030.⁴

The incidence of type 2 diabetes increases significantly with an increase in age, typically manifesting in middle age or the later part of life. The impacts of T2DM are considerable: as a lifelong disease, it increases morbidity and mortality and decreases the quality of life. At the same time, the disease and its complications cause a heavy economic burden for diabetic patients themselves, their families and society. A better understanding about the cause of a predisposition of Indians to get T2DM is necessary for future planning of healthcare, policy and delivery in order to ensure that the burdens of disease are addressed. India is home to over 61 million diabetic patients - an increase from 50.8 million last year. By 2030, India's diabetes burden is expected to cross the 100 million mark as against 87 million earlier estimated. The country is also the largest contributor to regional mortality with 983, 000 deaths caused due to diabetes this year. The International Diabetes Federation's (IDF) fifth diabetes atlas has released the staggering figures. IDF says India's prevalence of diabetes among 20-79 year olds is 9.2%. India is only second to China, which has 90 million diabetics (2011) that will increase to about 130 million by 2030. Calling India the diabetes capital of the world,⁵ According to the IDF Four in every five diabetics are between 40 and 59 years. Around 78, 000 children are developing type 1 diabetes every year. By 2030, one in every 10 adults will have diabetes.”

According to the IDF, the total number of people with diabetes this year reached a staggering 366 million with 4.6 million deaths. Healthcare spending on diabetes has reached \$465 billion, the number of diabetic patients in India more than doubled from 19 million in 1995 to 40.9 million in 2007 ⁶. It is projected to increase to 69.9 million by 2025. Currently, up to 11 per cent of India's urban population and 3 per cent of rural population above the age of 15 have diabetes. Diabetes affects all people in the society, not just those who live with it. The World Health Organization estimates that mortality from diabetes and heart disease cost India about \$210 billion every year and is expected to increase to \$335 billion in the next ten years ⁷. These estimates are based on lost productivity, resulting primarily from premature death.

Various studies have shown that the high incidence of diabetes in India is mainly because of sedentary lifestyle, lack of physical activity, obesity, stress and consumption of diets rich in fat, sugar and calories. The most prevalent is the Type 2 diabetes, which constitutes 95 per cent of the diabetic population in the country. In this, patients are non-insulin dependent and they can control the glucose in their blood by eating measured diet, taking regular exercise and oral medication. Worldwide, millions of people have Type 2 diabetes without even knowing it and if not diagnosed and treated, it can develop serious complications.

Complications of Diabetes mellitus

All forms of diabetes increase the risk of long-term complications ⁸ These typically develop after many years (10–20), but may be the first symptom in those who have otherwise not received a diagnosis

before that time. The major long-term complications relate to damage to blood vessels. We can categorise these complications of diabetes in two forms:

1. Macrovascular complication
2. Microvascular complication

Macrovascular complication

The main “macrovascular” diseases (related to atherosclerosis of larger arteries) are ischemic heart disease (angina and myocardial infarction), stroke and peripheral vascular disease.

Microvascular complication

Diabetes also causes “microvascular” complications—damage to the small blood vessels.

Diabetic retinopathy, which affects blood vessel formation in the retina of the eye, can lead to visual symptoms, reduced vision, and potentially blindness.

Diabetic nephropathy, the impact of diabetes on the kidneys, can lead to scarring changes in the kidney tissue, loss of small or progressively larger amounts of protein in the urine, and eventually chronic kidney disease requiring dialysis.

Diabetic neuropathy is the impact of diabetes on the nervous system, most commonly causing numbness, tingling and pain in the feet and also increasing the risk of skin damage due to altered sensation⁹. Together with vascular disease in the legs, neuropathy contributes to the risk of diabetes-related foot problems (such as diabetic foot ulcers) that can be difficult to treat and occasionally require amputation. In addition, diabetes results in a reduced quality of life,¹⁰ much higher rates of depression¹¹. and mental illness,¹² and enormous societal and economic costs.¹³

Biochemical changes in Diabetes

There are numerous biochemical disturbances associated with diabetes.¹⁴ In particular, enhanced polyol metabolism, protein kinase C- β (PKC- β) activation, elevated levels of oxidative stress, and advanced glycation (glycosylation) end-product accumulation have emerged as prime candidates thought to promote many of the complications of diabetes.¹⁵ Interestingly, early clinical changes associated with the development of DR occur simultaneously with, or can be predictive of, other diabetic complications.¹⁶⁻²⁰

Furthermore, tight control of blood glucose and blood pressure management has proven to be effective in reducing the development and rate of progression of all the major complications of diabetes.²¹⁻²³

Recent Studies for glycaemic control

The Diabetes Control and Complications Trial (DCCT) demonstrated that good metabolic control, resulting from intensive insulin therapy, reduced the risk of progression or development of retinopathy, nephropathy and neuropathy in type 1 diabetes²⁴. The United Kingdom Prospective Diabetes Study (UKPDS) showed that intensive glycaemic control in type 2 diabetes significantly reduced the risk of development and deterioration of microvascular complications.²⁵ The primary goal of the management of diabetes mellitus is the attainment of near normal glycaemia. The target for good glycaemic control recommended by the American Diabetes Association (ADA)²⁶.

is glycated hemoglobin A1c (HbA1c) < 7.0%.

Unmet needs with existing drugs

Lifestyle modification is the most cost-effective intervention for prevention of diabetes in high-risk groups in India²⁷. However, control of diabetes with diet, weight control and physical activity has been difficult and will not be sufficient for most of the patients. Moreover, the steady increase in the incidence of type 2 diabetes has significant socioeconomic implications²⁸.

Oral Antidiabetic Drugs (OADs)

An oral antidiabetic drug (OAD) is the first line of drug treatment for type 2 diabetes. However, the progressive nature of type 2 diabetes usually requires a combination of two or more oral agents in the long term, often as a prelude to insulin therapy. Safety and tolerability (notably hypoglycaemia), and weight gain often limit the optimal use of OADs. Insulin treatment is the cornerstone of diabetes management. It is the only means of achieving good glycaemic control in insulindeficient patients with type 1 diabetes. Insulin is also used as an intermittent or permanent therapy in some patients with type 2 diabetes. The UKPDS data showed that the current available treatment modalities were not satisfactory as evidenced by the high morbidity and mortality among subjects with type 2 diabetes²⁵.

Both OADs and insulin treatment increased the risk of hypoglycaemia. Weight gain was significantly higher in the intensive group with a sulphonylurea (SU) (chlorpropamide, glibenclamide or glipizide) or with insulin than in the conventional group with diet, and patients assigned insulin had a greater weight gain than those assigned chlorpropamide or glibenclamide. Studies in India indicate that more than 50% of people with diabetes have poor glycaemic control (HbA1c > 8%), uncontrolled hypertension and dyslipidaemia, and a large percentage have diabetic vascular complications²⁹⁻³².

Overall, diabetes care in India leaves much to be desired. Increased awareness amongst health professionals to improve the standard of diabetes care is urgently needed, along with the development of novel therapeutic agents that can effectively control diabetes and prevent the development and progression of its complications without compromising on safety. Type 2 diabetes is a complex, multifactorial disease. It is associated with progressive deterioration of β -cell function and insulin resistance²⁵.

The UKPDS and DCCT data showed that tight control of diabetes can significantly prevent the development of vascular complications²⁴⁻²⁵.

The UKPDS also suggested that 53% of type 2 patients would require insulin 6 years after diagnosis, and 75% of patients would require multiple treatments after 9 years²⁵.

Although insulin treatment is effective, its long-term use can lead to gains in fat mass, especially abdominal obesity, which may worsen insulin resistance. Moreover, repeated episodes of hypoglycaemia may cause major problems.

Diabetes Treatment: Newer trends

DM is defined by an absolute (type 1) or relative (type 2) deficiency of insulin. Type 2 DM is characterized by insulin resistance, abnormal hepatic glucose production, and progressive worsening of pancreatic β -cell function over time.²¹ Prevention and treatment of DM is a major public health challenges. Greater understanding of the pathophysiology of DM has contributed to the development of new

pharmacological approaches. The currently available classes of anti-diabetic agents are glucagon-like peptide-1 (GLP-1) receptor agonists, dipeptidyl peptidase-IV (DPP-4) inhibitors, thiazolidinediones (TZDs; glitazones), insulin analogues, biguanides, sulphonylureas, meglitinides, α -glucosidase inhibitors, and synthetic amylin analogues (Table 1). In addition, endocannabinoid antagonists acting at the CB1 receptor show promise for affecting food intake and improving glucose homeostasis. Insulin treatment, particularly with new basal formulations, is used increasingly in type 2 diabetics.

New agents—primary treatment :

- GLP-1 receptor agonists
- DPP-4 inhibitors
- Thiazolidinediones
- Insulin analogues, basal, and short-acting

Current proved agents—primary treatment :

- Biguanides
- Sulphonylureas

New agents—secondary treatment :

- Meglitinides
- α -Glucosidase inhibitors
- Synthetic amylin analogues

DPP-4 inhibitors include the oral drugs Januvia, Onglyza, and Tradjenta. These protect a natural compound in the body — *GLP-1* — from breaking down. GLP-1 helps lower blood glucose. *Incretin mimetics* or GLP analogs include the injected drugs Byetta and Victoza. They use the body's own signaling system to boost insulin after meals.

Other drugs include Symilin, an injectable synthetic hormone. It helps lower blood sugar after meals in people with diabetes who use insulin.

Combination drugs have made a difference. They join different medications in one pill — often metformin and a sulphonylurea, a meglitinide, a *DPP4 inhibitor*, a thiazolidinedione, or a thiazolidinedione in combination with a sulphonylurea. This cuts down the number of pills a person has to take. Combination drugs include Actoplus MET, Avandamet, Duetact, Glucovance, Metaglip, and PrandiMet. There can be drawbacks. They tend to cost more than generic drugs. They can also make it harder to fine-tune the treatment. New types of insulin allow some people to take just one injection of a long-acting insulin each day. That can be much easier than multiple injections of standard insulin. Future medications. Other classes of medication are in development. One type doesn't affect insulin, unlike most diabetes drugs. It blocks the body from reabsorbing glucose from urine, Current drugs available for the treatment of diabetes mellitus.

As part of the quest for newer agents, research has focused on insulin-independent mechanisms. The investigators concluded that addition of dapagliflozin to metformin provided a new therapeutic option. Sodium glucose co-transporter inhibitor One of the newest agents is dapagliflozin,³³ an SGLT2 inhibitor. Sodium-glucose co-transporter 2 (SGLT2) is located mainly in the proximal tubule of the nephron. It reabsorbs most of the glucose filtered by the glomerulus. Binding of dapagliflozin inhibits renal glucose reabsorption and promotes urinary glucose excretion. One study of more than 500 patients, who had inadequate diabetic control with metformin alone, found that the addition of dapagliflozin reduced HbA1c and FPG, with no increased risk in hypoglycaemia but with an increased incidence of genital infections.—insufficient data at present .While the FDA has not approved any drug from this class, it could in the future.

Conclusion

India has the largest number of diabetic patients in the world. The disease is such that it cannot be cured; only managed. Diabetes, which was once prevalent only among adults, is now found commonly in children due to change in lifestyle and imbalanced eating habits. It is one of the top five leading causes of death in most developed countries. A substantial body of evidence suggests that it could reach epidemic proportions particularly in developing and newly industrialized countries. Diabetes is a complex condition with a multitude of metabolic imbalances involving the regulation and utilization of insulin and glucose (sugar) in the body.

Diabetes is currently considered an epidemic disease that is largely preventable and treatable through diet, exercise and lifestyle changes. Considering the enormous burden due to diabetes in India, it is important to realize the cost-effective measures of diabetes care like early screening, tight metabolic control, monitoring of risk factors and assessing of organ damage. Published data from several epidemiological, experimental human and animal studies as well as the data from several mega trials like DCCT and UKPDS³⁴ have convincingly proved the importance of tight metabolic control in arresting and preventing the progression of target organ damage. In the last two decades there is better understanding of pathophysiology of type 2 diabetes and availability of newer oral drugs for diabetes, newer insulin and improved delivery systems should translate to improve diabetes control in a newer dimensions.

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