Diabetes Mellitus

1. Introduction

Diabetes is a global epidemic with 415 million people affected worldwide equivalent to the total population of the USA, Canada and Mexico. In recognition of this, the United Nations passed a resolution in 2006 declaring diabetes to be a major, global health threat; the first time this has ever happened for a non-infectious disease. At present 1 in 12 of the world population has diabetes and this is estimated to rise to 10% of the world's population by 2040.

Diabetes is a chronic endocrine disorder characterized by high blood glucose levels resulting from an inability to produce or utilize the pancreatic hormone, insulin.

It is generally classified as:

Type 1 Diabetes Mellitus (T1DM) – insulin dependent
This affects approximately 5-10% of those who suffer from diabetes.

Type 2 Diabetes Mellitus (T2DM)
This has traditionally been managed by weight control and/or oral medication but 60% of individuals with T2DM will require insulin within 5-10 years.

Although the hall mark of T1DM is pancreatic beta cell destruction usually leading to absolute insulin deficiency and T2DM is characterized by insulin resistance and ongoing decline in beta cell function, there may be some overlap between the two categories.

Every doctor, worldwide, has been educated in the diagnosis and management of diabetes and the most current information is available from the International Diabetes Federation, the American Diabetes Association, the European Association for the Study of Diabetes and NICE (see references).

2. Diagnosis and Best Practice Treatment

The diagnosis of diabetes is made if the patient satisfies any one of the following criteria and, in all cases of type 1 diabetes, treatment will involve regular injections of insulin. Although the differentiation of T1DM and T2DM is usually made clinically, measurement of diabetes related autoantibodies and c-peptide levels could be helpful.

Criteria for the diagnosis of diabetes

FPG ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.*
OR
2-h PG ≥200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*
OR
A1C ≥6.5% (48 mmol/mol). The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*
OR
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

* In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

T1DM is more likely to be diagnosed in childhood but can develop at any age. The onset of T2DM is generally in later life but there has been a recent upsurge in children and adolescents. In addition, the management of T2DM has undergone a radical overhaul with the implementation of a strategy that includes the use of insulin at a much earlier stage.

This is a strong contrast to the long-established practice of keeping patients on diet and oral medication for as long as possible, before considering the use of insulin.

Optimal T2DM management should maintain the HbA1c (glycosylated haemoglobin) below 7.0%. If the HbA1c rises above this level, despite diet and oral/injectable antihyperglycemic medications, or if they are not achieving glycemic goals, treatment with insulin is indicated and should not be delayed. Insulin may be used in conjunction with other antihyperglycemics. It may be provided as a basal insulin only or combined with mealtime insulin.

It should be noted that the HbA1c is a measure of glycaemia control over the previous 2-3 months and will not change rapidly when insulin is introduced. In addition, switching to insulin will normally result in a weight gain of around 4kgs, which may be of significance in athletes involved in weight sensitive sports. In this situation, patients may continue to take METFORMIN after starting insulin because this medication attenuates the weight gain associated with a switch to insulin. It is not uncommon to continue metformin, sodium–glucose cotransporter 2 (SGLT2) inhibitors, and/or glucagon-like peptide 1 receptor agonists (GLP-1 analogues), especially if using basal insulin alone.

Although insulin is not usually considered as the first therapy of choice in T2DM, it may be utilized in the initial treatment for newly diagnosed T2DM if the patient is symptomatic and/or have an HbA1c over 10% and/or the fasting blood glucose is consistently over 250mg/dl (5.5 mmol/L).

Despite vast expenditure on healthcare worldwide, management of T2DM remains woefully inadequate with patients spending an average of 5 years well outside the recommended glycaemia range before treatment is initiated. The latest standards of clinical practice entail the utilization of insulin therapy at a much earlier stage in the treatment continuum and this will directly impact the work of TUECs.

3. Prohibited Substances

Insulin is prohibited under S4 of the WADA Prohibited List—Hormone and Metabolic Modulators. All individuals with diabetes on insulin require a TUE.

4. Other Non-Prohibited Alternative Treatments

There are currently no alternatives to insulin.

5. Consequences to Health if Treatment is Withheld

Failure to utilize insulin in the treatment of patients with T1DM will result in the death of the patient.

As described above, in certain situations where T2DM is poorly controlled, insulin may be part of the recommended treatment regimen.

6. Treatment Monitoring

Once the initial diagnosis of T1DM or T2DM is made, patients will be regularly monitored by a doctor or diabetes educator to ensure that the dosage of insulin is adequate for glycaemic control.

7. TUE duration

The initial TUE request must include details of the onset, investigation and diagnosis of the condition, with supporting documentation from a specialist in the management of diabetes, or a unit specializing in the management of diabetes. It is recommended that for type 2 diabetes an initial TUE for insulin is granted for 12 months. After 12 months, the TUE should be reviewed with documentation obtained from the general practitioner and/or the specialist) and a further TUE may be granted for 10 years.

TUEs for type 1 diabetes may be granted for insulin for up to 10 years, with a documented review every few years by their general practitioner or specialist.

8. Any Appropriate Cautionary Matters

None.

References

1. The International Diabetes Federation (IDF), https://www.idf.org/

2. The American Diabetes Association (ADA), http://www.diabetes.org/

3. NICE – The National Institute for Health and Care Excellence, https://www.nice.org.uk/guidance/ng17

4. European Association for the Study of Diabetes (EASD), https://www.easd.org/statements.htmlDiabetes Canada Clinical Practice Guidelines Expert Committee. *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada*. Can J Diabetes. 2018;42(Suppl 1):S1-S325.