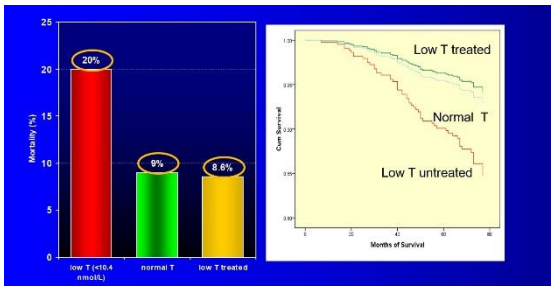

Association of British Clinical Diabetologists

The ABCD Worldwide Testosterone & Diabetes Audit Rationale for Audit Form

1. The Audit includes the input of **RETROSPECTIVE** historical data on patients as well as **PROSPECTIVE** on new patient data.
2. Inclusion
   (a) Patients diagnosed with hypogonadism (testosterone deficiency) commenced on testosterone replacement therapy.
   (b) Patients with hypogonadism (testosterone deficiency) not treated (declined, for clinical reasons etc.) and can also be included and follow up data can be used if available.
3. There is no limit on years of follow up. Longer term data may give important information. You can add as many clinic visits as the data you have with from each patient.
4. Complete the audit form with the data you have available from normal clinical practise. A completed form for all is not essential. Please enter details of your usual management of testosterone deficiency and diabetes. But you can use any of the tools within the audit as they are used in clinical practise.

The diagnosis of male hypogonadism is a combination of symptoms and biochemical evidence of testosterone deficiency.

SYMPTOMS

Treatment of hypogonadism should lead to improvement in symptoms and should be documented in normal clinical practise. This is usually done by entries into the patient's notes and/or using a formal questionnaire which is most commonly the Aging Male Symptom Score (AMS). The audit provides a series of 11 individual questions which may help the clinician to assess and record a patients' symptoms before and with ongoing testosterone replacement.

Symptoms are non-specific but can be divided into three main categories (1) sexual, (2) physical and (3) psychological. The audit tool can provide a score for ten questions which may help the clinician assess the individual's response to treatment. It is important to recognise that the score has not been validated but provides a combination of symptoms which may improve with testosterone replacement.

If a clinician uses the AMS questionnaire it can be used to populate the symptoms questionnaire s on the software tool and can insert the AMS total and domain scores. The AMS is not a diagnostic tool as it does not have adequate sensitivity and specificity. It is generally used as an adjunct to management.

The extra question not included in the total score on erectile response to PDE-5 inhibitor therapy is excluded but may be helpful for clinical management. Testosterone therapy has been reported to convert 50-60% PDE-5 inhibitor non-responders to responders.

INVESTIGATIONS

Two morning total testosterone levels (fasting as advised by national and international guidelines) at least one week apart are required to make a diagnosis. The calculated free testosterone (using the Vermuelen Formula within the audit tool) from the total testosterone and SHBG can be used in the clinical assessment (see Guidelines section).

If nmol/l (or other SI units in assay values) is not used, please calculate nmol/l from your units for conformity of data in the study.

LH and FSH can help in the determination of causality (Primary and Secondary Hypogonadism).

Haematocrit and PSA are important for safety assessment.

HbA1c, lipid profile, ALT and AST:ALT (surrogate markers of fatty liver) and creatinine and eGFR) to assess cardio-metabolic and renal function.

Weight and BMI (patient's height inserted on patient registration form) and BP. Waist circumference is an important risk factor for cardiovascular risk. So this value if done should be inserted.

Dexa Bone Scan. The commonest identifiable cause of osteoporosis in men is testosterone deficiency. Guidelines recommend that bone density is assessed when a man is diagnosed with hypogonadism at baseline. Then appropriate management can be introduced.

Diagnosis of Hypogonadism

It is important to understand what the different clinical causes of testosterone deficiency may be associated with type 2 diabetes.

Testosterone Therapy

This is to understand the roles and benefits of different formulations of testosterone replacement. Names of formulations outside the UK can be inserted under other formulations.

The audit will determine whether or not **normalisation** of testosterone levels on treatment are important to achieve he potential benefits to the patient. Guidelines advise that testosterone is replaced to achieve peak serum levels in the mid-normal healthy range.

Gels – The peak level is normally achieved between 24 hours after the gel has been applied. If there is a low testosterone on gel treatment, then it is important to check with the patient that he has had the blood taken at the correct time and if not the blood should be re-checked at the correct time after the gel has been applied.

If the testosterone level is very high, it maybe that the skin over the venepuncture site has been contaminated and that gel has entered the syringe. Again the blood will need to be repeated as it would be inappropriate to change the testosterone dose under these circumstance. If there is any

doubt measure oestradiol along with the testosterone. If the oestradiol is low compared to the testosterone, then this confirms contamination. If the oestradiol is high, then this confirms that the dose is too high as the absorbed testosterone is converted to oestradiol in vivo.

A note can be made in the text box if future fertility is required.

Diabetes and Complications

The following sections collect information in regard to diabetes which are included in standard clinical care. This includes brief information on the patient's mobility, physical and emotional effects on social activities. Also, how diabetes affects their life in general. The Diabetes Distress Screening Scale is assessed by diabetologists in clinical practise and has been successfully used in previous ABCD audits.

Baseline Medication

This information is routinely available in clinical practise. There is evidence that testosterone therapy can reduce diabetes medication in particular insulin dose and in some cases may lead to remission over time. In some patients this may become manifest with an increase in hypoglycaemic events. So this is an important event if present needs to be identified.

ABCD, December 2020