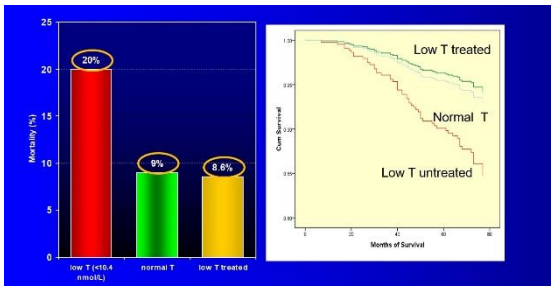

Association of British Clinical Diabetologists

The ABCD Worldwide Testosterone & Diabetes Audit Objectives

ABCD has constructed a worldwide audit to evaluate the real world role of testosterone in men with type 2 diabetes. The aim will be to ascertain data from experience in the use of testosterone replacement therapy in men diagnosed with hypogonadism (testosterone deficiency). Clinicians will be invited to submit the data that they routinely collect as they monitor the progress of their patients with hypogonadism treated or untreated to the worldwide audit. Based on technologies used in previous such audits, a secure, on-line, encrypted, IT tool is being developed to make this process as easy and user friendly as possible. It will also facilitate easy analysis of locally collected data by the local clinicians. ABCD hopes to gain insight into both the safety and efficacy of testosterone therapy and determine if there are any effects of testosterone deficiency if patients are not treated. ABCD hopes that the data from the worldwide audit will inform future practice and guidelines.

From the data submitted in the audit ABCD hopes it might be able to quantify and analyse in detail:

- How much ***improvement in clinical symptoms*** related to testosterone treatment occurs in real clinical use?
- Which ***types of patients*** are most likely to respond to testosterone in benefits to symptom resolution?
- What is the ***effect of testosterone replacement on erectile function*** and does it improve the response to PDE-5 inhibitors?
- To determine what ***causes of hypogonadism,*** occur in the diabetes population and the percentage of Classical v Functional causes?
- What percentage of patients achieve a ***reduction in HbA1c*** and to detect any parameters which may predict a responsive patient?
- To determine if testosterone therapy leads to ***a reduction in hypoglycaemic medication burden*** including total insulin daily dose.
- Is testosterone therapy effectiveness associated with ***other types of glycaemic therapy***?
- What is the ***risk of hypoglycaemia*** after commencing testosterone replacement particularly in patients who are insulin treated?

- Does the use of testosterone therapy reduce the number of patients progressing from oral hypoglycaemic medications to the ***addition of insulin***?
- In how many patients is testosterone therapy associated with ***remission of type 2 diabetes***?
- To determine the effect of testosterone replacement on ***weight, BMI and waist circumference*** in real clinical use?
- What is the impact of testosterone on ALT and AST/ALT ratio as a surrogate marker of ***hepatic steatosis***?
- What is the impact of testosterone on ***lipids*** in real clinical use?
- Is there any benefit on ***renal function*** - eGFR and creatinine?
- Does testosterone replacement improve the ability of patients to deal with the stress of living with their diabetes (***Diabetes Stress Screening Scale***)?
- Are there any benefits to the patients on their ***mobility, physical and social activities***?
- What percentage of patients have a history of ***hypertension and/or cardiovascular disease***?
- Does testosterone therapy effect ***cardiovascular event frequency***?
- What are the ***side effects*** of testosterone therapy?
- What is the incidence of ***secondary polycythaemia*** and how is it managed?
- What is the incidence of ***benign prostatic hypertrophy and prostate cancer*** in the diabetic population?
- How many patients on testosterone ***achieve normalisation of their testosterone levels*** i.e. achieving mid to high normal peak testosterone levels on gels and a trough testosterone within the lower normal range and not below on testosterone undeconoate long-acting depot injections?
- Are patients ***satisfied*** with their testosterone treatment?

ABCD, December 2020