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TESTOSTERONE REPLACEMENT THERAPY IN MEN WITH HYPOGONADISM AND TYPE 2 DIABETES ABCD (Association of British Clinical Diabetologists) WORLDWIDE AUDIT

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Financial Disclosures

Background

Male Hypogonadism is common in Type 2 Diabetes with a prevalence of 40% having symptoms of testosterone deficiency [1]. Testosterone deficiency is associated with reduced Quality of Life (QOL), sexual, physical and psychological health.
Furthermore, testosterone deficiency is associated with increased Cardiovascular Risk caused by Insulin Resistance, poor Glycemic control, Dyslipidemia and Visceral Obesity.
Testosterone therapy has been shown to be an insulin sensitizor reducing resistance as well as in some studies decreasing HbA1c but not all {2].
Testosterone therapy also increases muscle mass and decreases fat mass with very significant overall weight loss after 12 months.
Importantly patients with low testosterone have more than a two-fold increase in mortality compared to a diabetic man with normal testosterone statu s[3].
Testosterone replacement improves the survival to that compared that of a eugonadal diabetic patient.
THE T4D a large placebo controlled RCT over 2 years reduced progression of men with prediabetes to overt diabetes by 50% [4].
The TRAVERSE study (n=5200) FDA required Cardiovascular Safety study showed that testosterone therapy did not increase MACE events [5].

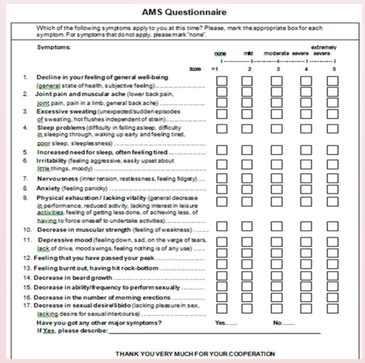
Objective

To determine the symptomatic response to testosterone therapy in men with hypogonadism and type 2 diabetes. 2. To assess any effect on B=HbA1c, lipid profile, BMI, waist circumference, BP using data fromtests routinely checked in routine clinical care .

Methods and Material

Clinical Centres treating men with Diabetes were recruited to input routine clinic data on patients assessed for Testosterone Deficiency. Patient identifying data was encrypted by each participating centre. Specific new and follow up audit forms online provided by ABCD. Data only included from routine clinical practise. Each centre can independently audit their own data.

Periodic data evaluated as aim is to eventually collect more patient inputs to be able to determine differences in response to several parameters. The current presentation gives interim data collected 196 evaluable patients for HbA1c, Weight, Waist circumference and AMS symptom and QoL score.(Fig 1)



AMS Questionnaire

Which of the following symptoms apply to you at this time? Please, mark the appropriate box for each symptom. For symptoms that do not apply, please mark 'none'.

Symptoms:

Score	none =1	mild 2	moderate 3	severe 4	extremely severe 5
1. Decline in your feeling of general well-being (general state of health, subjective feeling)	☐	☐	☐	☐	☐
2. Joint pain and muscular ache (lower back pain, joint pain in a limb, general back ache)	☐	☐	☐	☐	☐
3. Excessive sweating (unexpected/sudden episodes of sweating, hot flushes independent of strain)	☐	☐	☐	☐	☐
4. Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early and feeling tired, poor sleep, sleepiness)	☐	☐	☐	☐	☐
5. Increased need for sleep, often feeling tired	☐	☐	☐	☐	☐
6. Irritability (feeling aggressive, easily upset about little things, moody)	☐	☐	☐	☐	☐
7. Nervousness (inner tension, restlessness, feeling fidgety)	☐	☐	☐	☐	☐
8. Anxiety (feeling panicky)	☐	☐	☐	☐	☐
9. Physical exhaustion / lacking vitality (general decrease in performance, reduced activity, lacking interest in leisure activities, feeling of getting less done, of achieving less, of having to force oneself to undertake activities)	☐	☐	☐	☐	☐
10. Decrease in muscular strength (feeling of weakness)	☐	☐	☐	☐	☐
11. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings, feeling nothing is of any use)	☐	☐	☐	☐	☐
12. Feeling that you have passed your peak	☐	☐	☐	☐	☐
13. Feeling burnt out, having hit rock-bottom	☐	☐	☐	☐	☐
14. Decrease in beard growth	☐	☐	☐	☐	☐
15. Decrease in ability/frequency to perform sexually	☐	☐	☐	☐	☐
16. Decrease in the number of morning erections	☐	☐	☐	☐	☐
17. Decrease in sexual desire/libido (lacking pleasure in sex, lacking desire for sexual intercourse)	☐	☐	☐	☐	☐

Have you got any other major symptoms? Yes..... No.....
If Yes, please describe:_____

THANK YOU VERY MUCH FOR YOUR COOPERATION

Figure 1

AMS QoL for Hypogonadism

Sexual
Physical
Psychological
Domains

CURRENT AUDIT RECRUITMENT
40 Centres in 10 Countries mainly UK but also in Germany, Canada, Brazil, South Africa, New Zealand, Malaysia, Vietnam
Patients 460
Three Year evaluable paired data from **196** patients (with up to 24 months data.

Testosterone Formulations – Testosterone Undeconoate (Nebido®) long-acting i/m injection, Testosterone gels (Testogel®, Tostran®).

Summary or Results

BASELINE DATA (n=196)

Mean Age 70.7± 9.35 years

Weight 114.24 + 17.54 kg

Waist Circumference 104.8 + 16.8 cm

Testosterone 9.22 ± 1.74 nmol/l

Aging Male Symptom Score (AMS) 40.83/85
Normal Range <30/85

Diabetes Medication Changes – Not yet assessed

HbA1c (%)

* P=<0.001		HbA1c (%)		
		6 Month (n=163)	12 Month (n=145)	36 Month (n=125)
Time (Months)	0	8.6%	8.6%	8.6%
	3	8.1%*		
	12		7.7%*	
	24			6.9%*

Statistical Analysis – t test: Paired two sample means, Pearson Correlation.

HbA1c (mmol/mol)

* P=<0.001		HbA1c (mmol/mol)		
		6 Month (n=163)	12 Month (n=145)	36 Month (n=125)
Time (Months)	0	70.51	70.82	70.99
	3	64.96*		
	12		61.06*	
	24			51.7*

Statistical Analysis – t test: Paired two sample means, Pearson Correlation.

Figure 2.Effect of TRT on HbA1c up to 36 months

Figure 3 Effect of TRT on Symptoms and QoL

	Baseline	12 Months	P value
Weight (kg)	112.6	107.15	0.61
Waist Circ(cm)	116.08	115.12	0.43

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Conclusion

1.Testosterone Replacement Therapy (TRT) for Diabetic Men with Hypogonadism improves **Symptoms** and **Quality of Life** in of testosterone deficiency. This benefit persist for at least 12 months.
2. TRT also has an **add-on benefit in the control of glycemia,** significantly lowering HbA1c over a 2-year follow up period.
3. At one-rear there was effect on weight and waist circumference which is not unexpected as the increase in Muscle Mass cancels out the reduction in Fat Mass. This phenomenon has been shown in many RCT's of TRT.
4. These are preliminary results from an on-going audit which plans to collect data from over one thousand patients worldwide. This will enable us to identify which type of patients responds to TRT.

References

1 Kapoor D et al. Diabetes Care 2007:30;911-17

2 Jones TH et al. Diabetes Care 2011:34;828-37

3 Muraleedharan V et al. Eur J Endocrinol 2013:169;725-33

4. Wittert G et al. Lancet Diab Endocrinol 2021:9;32-45

5. Lincoff AM et al. NEJM 2023:389;107-117

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