

TESTOSTERONE REPLACEMENT THERAPY IMPROVES GLYCAEMIC CONTROL AND SYMPTOMS IN MEN WITH TYPE 2 DIABETES – THE ABCD WORLDWIDE AUDIT

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BACKGROUND

1. Symptomatic Testosterone Deficiency in men with Type 2 Diabetes is common affecting ~40% [1].
2. Testosterone deficiency is associated with a reduced Quality of Life and Sexual Health, poor Glycaemic Control, Dyslipidaemia increased Adiposity, muscle loss, osteoporosis and fatigue.
3. There is an increased risk of mortality, dementia and cardiovascular events.

Testosterone replacement therapy (TRT) improves insulin resistance, glycaemic control (in some studies), lipid profile and cardiovascular risk factors including beneficial effects on inflammation [2,3,4,]. Testosterone has been shown to reduce the progression of prediabetes to overt T2DM over two years by 50% in men with low testosterone [5].

AIMS

The aim of this worldwide audit is to determine the symptomatic response to testosterone therapy in men with hypogonadism and type 2 diabetes.

Using data collected during routine clinical care, to also assess any effect of testosterone therapy on HbA1c, lipid profile, BMI, waist circumference, blood pressure and safety.

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WORLDWIDE AUDIT**



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**YOU CAN AUDIT YOUR OWN PRACTICE USING
THE AUDIT TOOL AS WELL AS PROVIDE THE
ENCRYPTED ANONYMISED PATIENT DATA**

METHODS

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 (see www.abcd.care/audit/abcd-testosterone-diabetes-worldwide-audit/).

Data only included from routine clinical practise. Each centre can independently audit their own data.

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 202 patients (with up to 24 months data for AMS score and 36 month data for HbA1c. Testosterone Formulations – Testosterone Undeconoate (Nebido®) long-acting i/m injection, Testosterone gels (Testogel®, Tostran®, Testavan®).

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	None	1	2	3	4
1. Decline in your feeling of general well-being (general state of health, subjective feeling).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Joint pain and muscular aches (lower back pain, joint pain, pain in a limb, general back aches).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Excessive sweating (unexpecting/undesired episodes of sweating, hot flashes independent of stress).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Sleep problems (difficulty in falling asleep, difficulty in sleeping through, waking up early and feeling tired, poor sleep, sleeplessness).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Increased need for sleep, often feeling tired.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Irritability (feeling aggressive, easily upset about little things, moodiness).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Nervousness (inner tension, restlessness, feeling fidgety).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Anxiety (feeling panicky).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Physical exhaustion (lacking vitality (general decrease in performance, reduced activity, lacking interest in leisure activities, feeling of getting less done, achieving less of having to force oneself to undertake activities).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Decrease in muscular strength (feeling of weakness).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Depressive mood (feeling down, sad, on the verge of tears, loss of drive, mood swings, feeling nothing is of any use).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Feeling that you have passed your peak.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Feeling burnt out, having hit rock-bottom.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Decrease in beard growth.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Decrease in ability/eagerness to perform sexually.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Decrease in the number of morning erections.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Decrease in sexual desire/libido (lacking pleasure in sex, libido).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you got any other major symptoms? If So, please describe: Yes..... No.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

THANK YOU VERY MUCH FOR YOUR COOPERATION

FIGURE 1

SCORING of AMS

17-26 = Normal/low symptoms,
27-36, mild symptoms,
37-49, moderate symptoms,
>50 Severe symptoms

BASELINE DATA

Mean Age 70.7+ 9.35 years
Weight 114.24 + 17.54 kg
Waist Circumference 104.8 + 16.8 cm
Testosterone 9.21+ 1.75 nmol/l

RESULTS

Effect of TRT on Weight & Waist Circumference

	Baseline	12 months	p value
Weight (kg)	112.6	107.15	0.6
Waist (cm)	116.08	115.12	0.43

AMS SYMPTOMS TOTAL SCORE * P=<0.001

Time (Months)	AMS TOTAL SCORE			
	3 Month	6 Month	12 Month	24 Month
	(n=168)	(n=202)	(n=174)	(159)
0	55.86	55.95	54.5	54.12
3	27.39*			
6		27.32*		
12			21.74*	
24				19.09*

Fig 2 Effect of Testosterone Replacement Treatment on Symptoms of Hypogonadism

GLYCAEMIC CONTROL HbA1c *P<0.005

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

Fig 3 Effect of Testosterone Replacement Therapy on HbA1c

Statistical Analysis – t test: paired two sample means, Pearson Correlation * P=<0.001

CONCLUSIONS

1. Testosterone Replacement Therapy (TRT) for Hypogonadal men with Type 2 Diabetes improves Symptoms and Quality of Life.
2. This benefit persists for at least 24 months.
3. TRT also has an add-on benefit in the control of glycemia, significantly lowering HbA1c over a 3-year follow up period.
3. At one-year 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 respond to TRT.
Safety – RCT's including large studies have not shown any significant increase in the risk of Major Cardiovascular Events (MACE) or Prostate carcinoma [10] when patients are treated to attain normal testosterone levels.. The small increases in atrial fibrillation, deterioration in renal function and thromboembolism in the Traverse trial have been shown to be due to Covid in this study group whereas those without a Covid infection had no significant increase in adverse effects of these parameters [11].
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