TESTOSTERONE THERAPY IMPROVES QUALITY OF LIFE AND SEXUAL HEALTH REPLACEMENT IN HYPOGONADAL MEN WITH TYPE 2 DIABETES – THE ABCD WORLDWIDE AUDIT

TH Jones[1,2], A Haider[3], KS Haider[3], U Dashora[4], REJ Ryder[5]

[1]Barnsley Hospital, Centre for Diabetes and Endocrinology, Barnsley S75 2EP, [2]Division of Clinical Medicine, Medical School, University of Sheffield, Sheffield S10 2RX, [3]Urology, Bremmerhaven, Germany, [4]Conquest Hospital, Hastings, [5]Dudley Road Hospital, Birmingham

Introduction

- Symptomatic Testosterone Deficiency in men with Type 2 Diabetes is common affecting ~40% [1]. Testosterone deficiency is associated with a reduced Quality of Life and Sexual Health, poor Glycaemic Control, Dyslipidaemia increased Adiposity, muscle loss, osteoporosis and fatigue. 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].
- Testosterone Therapy has been shown to reduce 6-year mortality by over half of treated patients compared to untreated patients with diabetes and hypogonadism [6].

- **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.

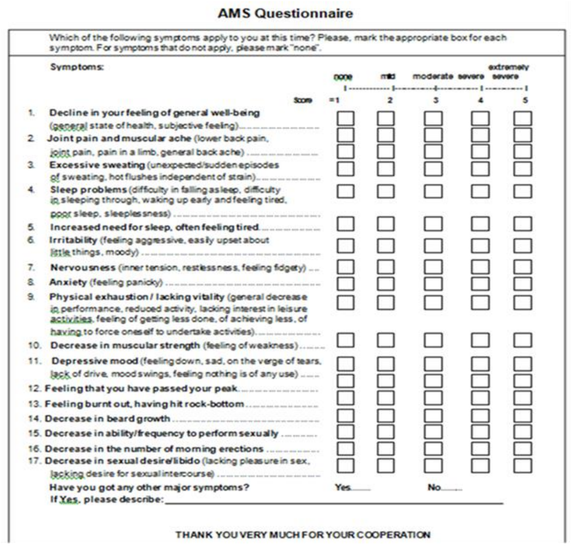
- Hypogonadism / Symptomatic Testosterone Deficiency is defined as a syndrome complex which comprises symptoms± signs and biochemical evidence of testosterone deficiency [7].
- Guidelines state that in symptomatic patients **two** fasting morning (before 1000h) testosterone levels (taken at least 7 days apart) <8nmol/l are consistent with hypogonadism, 8.1-12nmol/l a trial of TRT is indicated for at least 6 months [7,8].
- Testosterone assay ranges can differ between commercial assays and hospitals. The Society for Endocrinology and the Association of British Clinical Chemists have advised a Standardisation of normal ranges in line with the guidelines [9].

- The Aging Male Symptom (AMS) Score (Figure 1) is a validated questionnaire for Quality of Life (QoL) in men with hypogonadism and can assess the effect of TRT on symptom improvement.

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.

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, 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, sleeplessness)		☐	☐	☐	☐	☐
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

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®).

RESULTS

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

Effect of TRT on Weight and Waist Circumference

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

AMS SYMPTOMS TOTAL SCORE
*** P=<0.001**

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

Figure 2 Effect of Testosterone Replacement Treatment on Symptoms of Hypogonadism

SCORING of AMS 17-26 = Normal/low symptoms, 27-36, mild symptoms, 37-49 moderate symptoms, **>50 Severely symptomatic**.

GLYCAEMIC CONTROL HbA1c
***P<0.005**

		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*

Figure 3 Effect of Testosterone Replacement Therapy on HbA1c

Statistical Analysis – t test: Paired two sample means, Pearson Correlation. Not corrected for changes in medication including insulin.

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].

PLEASE JOIN THE AUDIT

This is an ongoing audit which aims to get large numbers of patients with testosterone who have either been treated with any formulation of testosterone and in addition patients with testosterone deficiency who have not been treated and followed. The data entered into the forms can be minimal if time is a problem. Not all questions need to be answered. It is important to enter data for diagnosis and HbA1c with alterations in medications. The more data the better.

INDIVIDUAL CLINICIANS CAN AUDIT THEIR OWN PATIENTS

High recruiters will have their names on publications and posters.

www.abcd.care/audit/abcd-testosterone-diabetes-worldwide-audit/

ABCD Testosterone & Diabetes Worldwide Audit

ABCD worldwide audit of testosterone deficiency in men with type 2 diabetes

Register for this audit
Worldwide Testosterone and Diabetes Audit
Data Collection Forms
Download first visit data entry form
Download follow up visit data entry form

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Disclosures

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- Grunenthal – Travel Grant
- Kyowa-Kirin (now Advanz) Honoraria Educational Filming
- Androlabs – Honoraria for Advisory Boards
- Mereo Biopharma - Consultancy