

# “Long-term monitoring of hypogonadal men receiving intramuscular testosterone replacement: a retrospective audit”

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## ABSTRACT

**Background:** Intramuscular long acting testosterone injections are widely used, convenient form of androgen replacement in patients with hypogonadism.

**Aims:** To evaluate the long term effects of parenteral long acting testosterone replacement on patients commenced on treatment in years 2006-2014 and adherence to monitoring undertaken by primary care after discharge from specialist service.

**Method:** We reviewed the results of 64 patients (mean age 58.5 years). Indications for starting testosterone treatment were both primary and secondary hypogonadism. Patients were followed up for an average of 4.33 years (between 3 months and 9 years). Total follow up time was 277.2 patient-years. 53 patients continued with treatment, 7 patients discontinued the treatment and 4 patients died during the follow up period time. We followed the changes of the following blood tests: alanine transaminase (ALT), aspartate transaminase (AST), total cholesterol (TC), haematocrit (HCT), haemoglobin (Hb), prostate-specific antigen (PSA) and testosterone. Adherence to the advised monitoring intervals of these parameters was reviewed.

**Results:** Over the follow up period time the mean changes in the results were as follows: ALT +1.05 IU/L (+5%), TC -0.41 mmol/L (-8.1%), HCT +0.030 (+7.0 %), Hb +7.06 g/L (+4.9%), PSA +0.91 µg/L (+96%), testosterone +19.2 nmol/L (+206%).

Adherence to the monitoring intervals advised by our specialist service was: ALT 78.9%, HCT and Hb 80.3%, PSA 52.2% and testosterone 66.3%.

**Conclusions:** Long acting parenteral testosterone replacement in our group of patients resulted in insignificant changes in liver function tests, haematocrit and haemoglobin. We observed a rise in PSA levels, although the mean value remained in the normal range. Reduction of TC levels was noticed and testosterone replacement is reported in the literature to have no adverse effects on lipid profiles. Adherence to the advised monitoring intervals, especially for PSA and testosterone levels needs further attention.

## INTRODUCTION

Reduced androgen levels may have psychological, somatic and sexual effects influencing patient’s general well being<sup>1,3</sup>. Intramuscular long acting testosterone injections are widely used, convenient form of androgen replacement in patients with hypogonadism.

## AIMS:

To evaluate the long term effects of parenteral long acting testosterone replacement on patients commenced on treatment in years 2006-2014 and adherence to monitoring undertaken by primary care after discharge from specialist service.

## Group characteristics

Number of patients	64
Patients’ average age [years]	58.5
Patients’ average age [years] at start of testosterone	54.6
Total follow up period [patient-years]	277.2
Average follow up period [years]	4.33

## METHOD

During the follow up time – out of 64 patients:

- 53 patients continued with the treatment,
- 7 patients discontinued the treatment
- 4 patients died during the follow up period time.

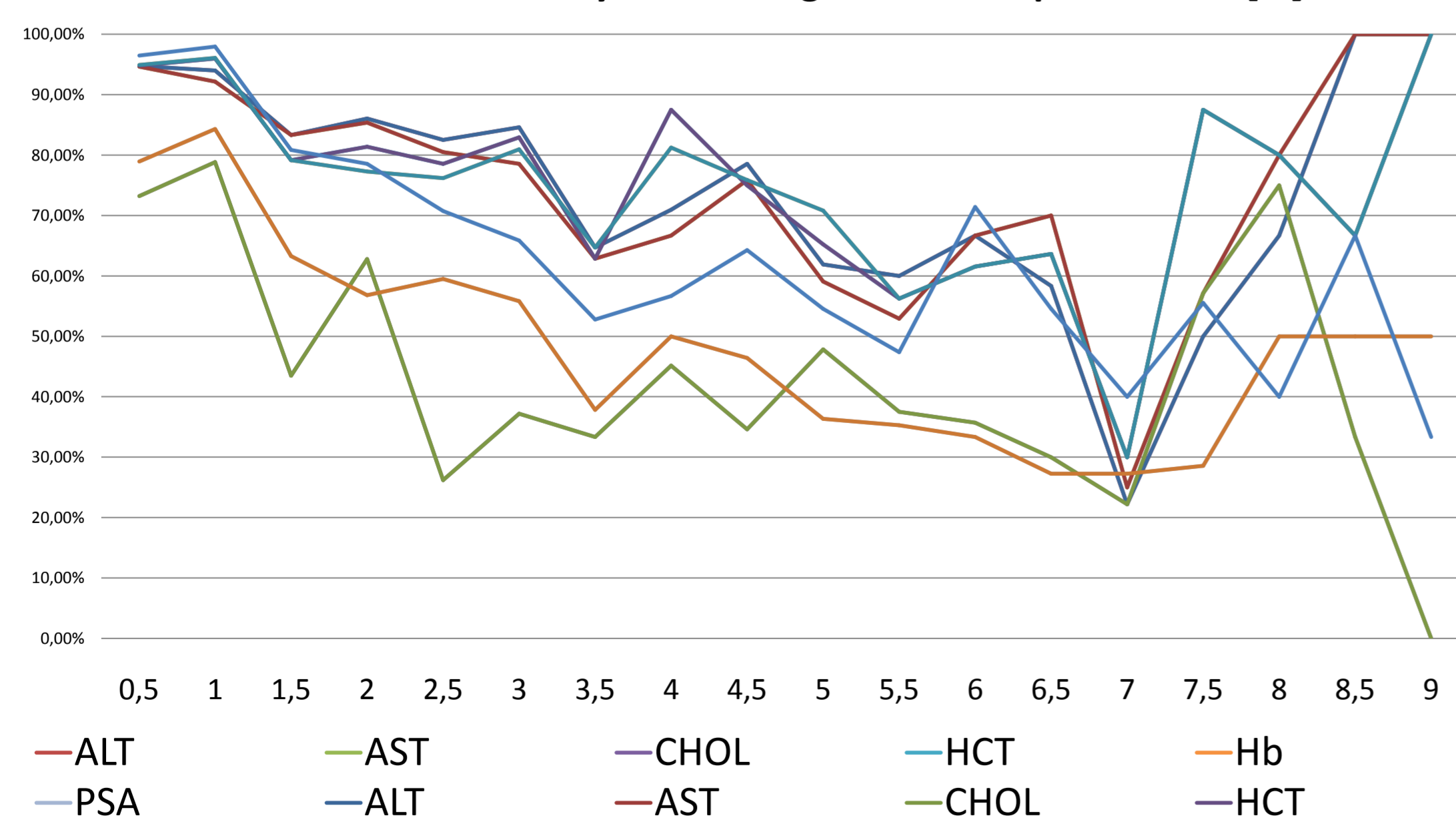
We reviewed the adherence to the advised monitoring intervals of the following parameters by primary care after discharge from specialist service.

## Parameters followed up :

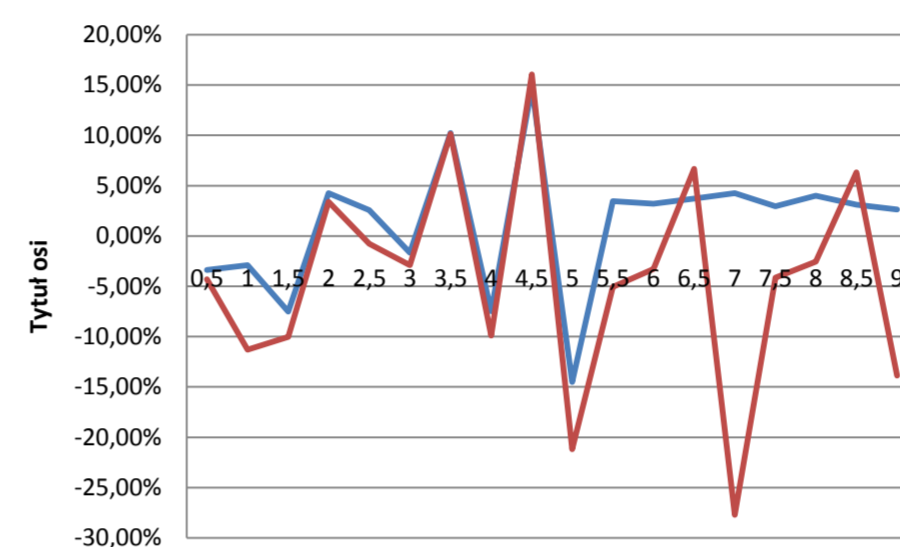
- alanine transaminase (ALT),
- aspartate transaminase (AST),
- total cholesterol (TC),
- haematocrit (HCT),
- haemoglobin (Hb),
- prostate-specific antigen (PSA)
- testosterone

## RESULTS

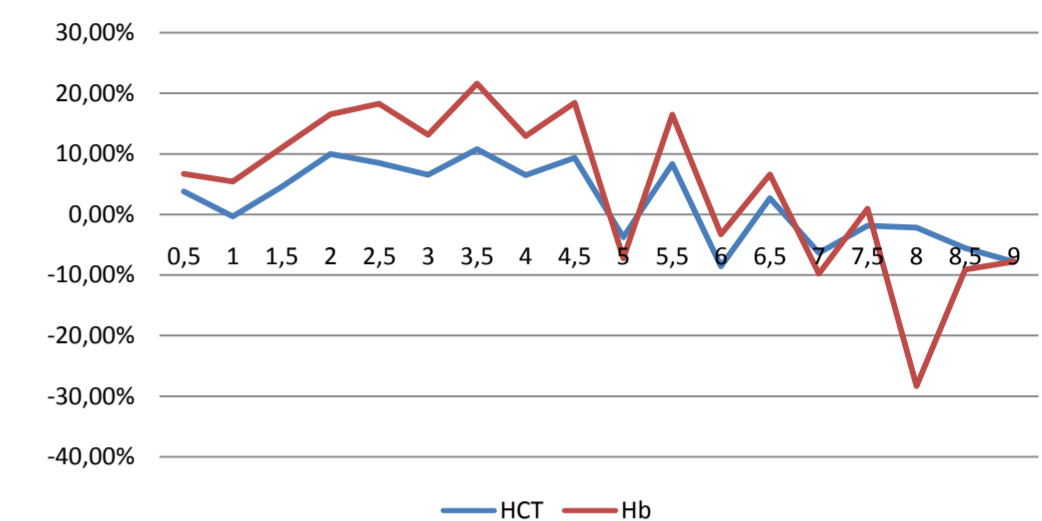
### Adherence to 6-monthly monitoring of selected parameters [%]



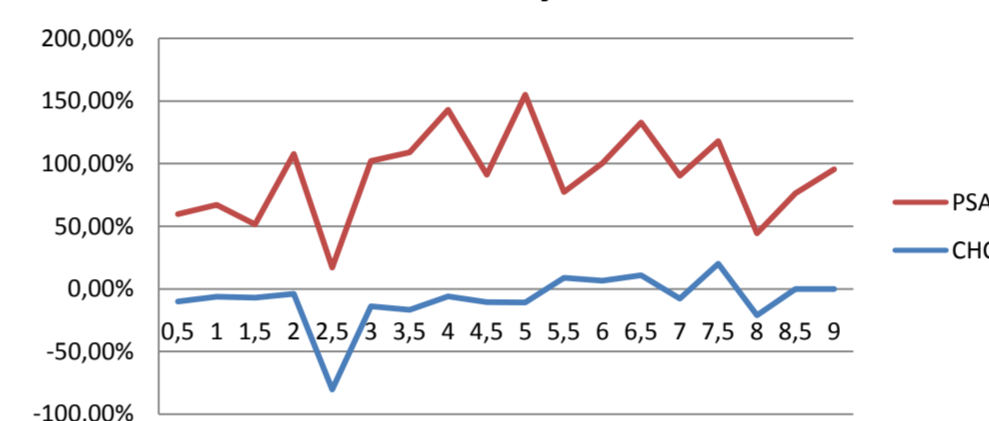
### Mean change of ALT, AST [%] over 9 years



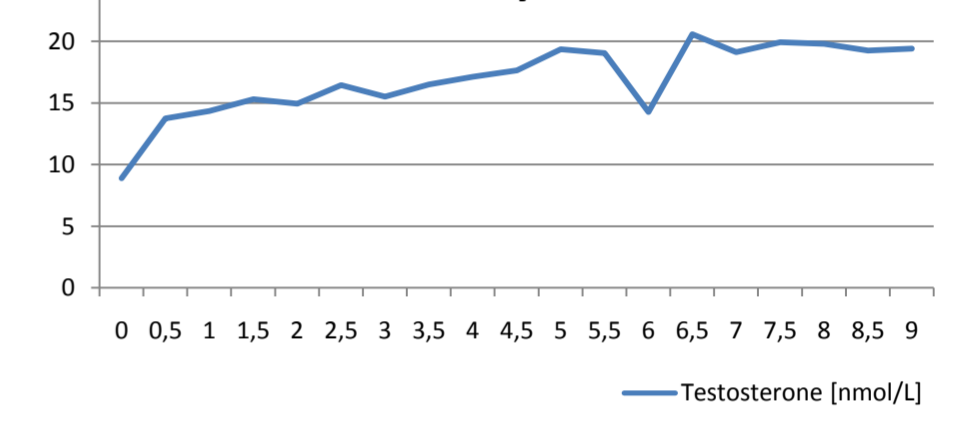
### Mean change of HCT, Hb [%] over 9 years



### Mean change of PSA, cholesterol [%] over 9 years



### Mean testosterone levels [nmol/L] over 9 years



	ALT	AST	Cholesterol	HCT	Hb	PSA	Testosterone
Mean parameter checks [%]	73.60	73.9	45.5	74.9	74.6	48.4	62.6
Mean parameter change [%]	4.40	7.4	-6.4	7	4.6	97.9	208.1

	Ageing Males' Symptoms scale (AMS)			International Prostate Symptom Scale (IPSS)		
	Mean value	[%] checked	change [%]	Mean value	[%] checked	change [%]
Baseline	45,24	57,8		11,20	54,7	
6 months	37,00	34,4	-19,8	9,44	28,1	-187,5
12 months	41,00	21,9	-22,6	7,83	18,8	57,2

## DISCUSSION

During the follow up period (on average 4.3 years), on long acting parenteral testosterone replacement we have not observed significant changes in the levels of alanine transaminase (ALT), aspartate transaminase (AST). This is consistent with the reports in the literature, as the unfavorable hepatic effects do not appear to be associated with intramuscular injections<sup>1</sup>.

We observed only slight increase in the levels of both haematocrit (HCT) and haemoglobin (Hb), 7% and 4.6% respectively. Out of total of 371 checks of HCT, only 5.1 % were in the polycythaemic range (HCT above 51%), which is lower than observed elsewhere<sup>5</sup>. Reduction of total cholesterol levels by 6.4% during the follow up period time was noticed. This is concordant with the results reported in the literature, where either no significant changes or slight reduction in total cholesterol were found regardless of mode of testosterone replacement<sup>2,5,6</sup>.

We observed a rise in PSA levels, although the mean value remained in the normal range. Out of the total of 269 checks of PSA, only 5.2% were above the level of 4 µg/L warranting referral for urological review or prostate biopsy<sup>4,7</sup>. 3 of our patients were eventually referred for further urological assessment. We have observed the reduction of the International Prostate Symptom Scale (IPSS) by 187% in the first 6 months of the follow up.

Adherence to the monitoring intervals advised by our specialist service was: ALT 74%, HCT and Hb 75%, PSA 48% and testosterone 63%. Adherence to these advised monitoring intervals, especially for PSA and testosterone levels needs further attention

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