

Testosterone Treatment in elderly Hypogonadal Patients does not increase prostate cancer risk: Results of a prospective comparative study. 6 years follow up analysis to Age-Matched Controls

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Objective:

Evaluating CaP prevalence in elderly hypogonadal subjects under TRT compared with age-matched control group

Methods: 154 hypogonadal patients (58 ± 1.7 years) received injectable long-acting TU 1000 mg, compared to 160 eugonadal men (59 ± 2.8 years) visiting clinic for check up. Monitoring included co-morbidities, medication, International Prostate Symptom Score (IPSS), PSA, digital rectal examination (DRE), prostate volume measured by transrectal ultrasound (TRUS). Biopsies were performed at PSA velocity $> 0.75 \mu\text{g/L}$

Results: Hypogonadal patients have lower PSA and smaller prostates ($0.68 \pm 0.4 \mu\text{g/L}$ and 25.6 ± 1.4 ml). Control subjects had initially PSA of $2.42 \pm 1.2 \mu\text{g/L}$, and prostate volume 38.4 ± 2.42 ml. Patients with PSA velocity in the observation period was $> 0.75 \mu\text{g/L}$, underwent TRUS-guided biopsies. In TRT group 5/22 who underwent biopsies showed CaP, three of them unilateral with up to 10% tumor cells in a core. Gleason scores were 3+2 or 3+3. In the 160 control subjects, 16/39 who underwent biopsies showed CaP, 4 of them bilateral, with a significantly higher Gleason score of 3+3 till 4+5 and up to 80% tumor cells in a core. No subject of both groups showed any abnormality in rectal palpation.

Conclusions:

Hypogonadal subjects have smaller prostates and lower PSA than eugonadal ones. TRT doesn't increase CaP incidence. TRT group had smaller tumors and less malignancy. Hypogonadism offers no protection against the development of biopsy-detectable prostate cancer. Lower levels of testosterone were associated with an increased risk of cancer.

**Table 1 (6 years)
Pathological Results of Biopsies**

	<i>Group I, N= 154 (hypogonadal and ED)</i>	<i>Group II, N= 160 (control)</i>
Number of biopsies	22	39
Prostate cancer	5	16
Unilateral	3	2
Bilateral	2	14
% tumor cells	10	up to 80
Gleason score	3+2 / 3+3	3+3 to 5+4
others	2 high-grade PIN	7

**Table 2 (6 years) 5/154 CaP Cases
Post-Surgical Outcomes TRT Group**

	Group I, N= 154 (hypogonadal/ED TRT=TU 1000mg im)				
Patient no.	1	2	3	4	5
PSA	2.91	2.44	2,34	1,99	3,17
Tumor stage	pT2a	pT2a	pT2c	pT2b	pT2a
Grading	GII	GII	GII	GII	GII
Gleason score	3+3	3+2	2+3	3+3	3+3
Lymph nodes	0	0	0	0	0
Surgical margin	neg	neg	neg	neg	neg
Bone metastases	0	0	0	0	0

**Table 3/ I (6 years) 16/160 CaP Cases
Post-Surgical Outcomes Control Group**

	Group II (control), N= 160						
Patient no.	1	2	3	4	5	6	7
PSA	8,06	3.75	3.2	10.6	4.79	5.42	3.79
Tumor stage	pT2b	pT2c	pT2c	pT2c	pT3a	pT3a	pT2c
Grading	GIII	GII	GIII	GIII	GIII	GIII	GIII
Gleason score	4+3	3+3	3+4	3+4	3+4	4+4	3+4
Lymph nodes	0	0	0	0	0	+	0
Surgical margin	pos	neg	neg	neg	pos	neg	neg
Bone metastases	0	0	0	0	0	0	0

**Table 3/ II (6 years) 16/160 CaP Cases
Post-Surgical Outcomes Control Group**

	Group II (control), N= 160						
	8	9	10	11	12	13	14
PSA	5,34	3,23	10,44	8.66	4.99	9,6	6,15
Tumor stage	pT3b	pT2c	pT3c	pT3b	pT2c	pT3b	pT3a
Grading	GIII	GII	GIII	GIII	GII	GII	GIII
Gleason score	4+3	3+3	5+4	3+4	3+3	3+4	3+4
Lymph nodes	0	0	+	0	0	0	0
Surgical margin	pos	neg	pos	neg	neg	neg	pos
Bone metastases	0	0	0	0	0	0	0

**Table 3/ III (6 years) 16/160 CaP Cases
Post-Surgical Outcomes Control Group**

	Group II (control), N= 160	
Patient no.	15	16
	2,42	
Tumor stage	pT2c	pT2c
	GII	GII
Gleason score	3+3	3+3
Lymph nodes	0	0
Surgical margin	neg	neg
Bone metastases	0	0