Testosterone undecanoat 1000 mg at 3 months does not increase Prostatic Specific Antigen level. Study on over 100 patients – December 2012

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Aim. To find if testosterone undecanoat 1000 mg injection (Nebido[R]; Bayer-Schering) has a negative effect on prostate.

Material&Method. 1. PSA (ng/ml) was registred retrospective (from files) and prospective analysis (onset 2010)**. 2.** From over 200 patients to whom testosterone undecanoat 1000 mg, i.m. was administrated at 3 months, in the last 7 years, and to whom the prostatic volume was quantified, 2096 PSA analysis were done before and after treatment. PSA was recorded (if possible) at T1 to T10 [2 weeks to 7 years] (see Pisoschi, this Congress); at least two analysis were registred. **3.** None patient with prostatic cancer was included. **4. Statistical analysis:** Student test, simple correlation, multiple regression.

Results. **A.** Patients at onset: 143 men, 18-96 years, average: 60.38; median: 60. **B.** Prostatic volume (cmc): average: 34.81. **C.** Average PSA (no pts): a. before treatment = = 1,60 (143); 1y = 1,69 (99); 2y = 1,4 (73); 3y = 1,85 (48); 4y = 2 (38); 5y = 1,86 (26); 6y = 1,51 (10); 7y = 2,86 (6).

	T0	T1- 2 w	T2 – 3 m	T3 – 6 m	T3 bis – 9 m	T4 – 1 y	T5 – 2 y	T6 – 3 y	T7 – 4 y	T8 – 5 y	T9 – 6 y	T10 – 7 y
Average	1,59	1,78	1,71	1,74	1,80	1,80	1,63	1,78	1,91	1,75	1,44	2,52
SD	1,53	2,17	1,75	2,22	2,08	1,69	1,16	1,53	2,96	1,64	1,89	4,29
No	141	34	29	34	25	101	73	48	38	26	10	6
T value vs T0		0,32	0,85	0,74	0,72	0,48	0,31	0,35	0,44	0,52	0,89	0,60

D. Statistical difference of average: nonsignificant for all the times from 2 weeks to 7 years.

E. Correlation between age and PSA was: 1. significant before and after treatment till to 2 years but nonsignificant for 3 to 7 years (PSA did not change as age after treatment).

F. Correlation between PSA and prostatic volume was significant, both before and after treatment.

	Correlation Age-PSA								Correlation Prostatic Volume-PSA							
	Before	1 y	2 ys	3 ys	4 ys	5 ys	6 ys	7 ys	Before	1 y	2 ys	3 ys	4 ys	5 ys	6 ys	7 ys
r	0,33	0,32	0,25	0,13	0,00	0,17	0,21	0,84	0,56	0,51	0,55	0,42	0,11	0,572	-0,06	0,52
p	<0,001	< 0,01	0,05	>0,1	>0,1	>0	1	>0	< 0,001	< 0,001	< 0,001	< 0,05	< 0,001	< 0,01	>0,1	>0,1

G. Multiple regression test (table) shows that PSA level post testosterone does not depend on testosterone **but** on age, prostatic volume (before and after treatment) and PSA initial level (before testosterone administration).

	Observations	R^2	F	P
1 year TUD	99	0,53	36,36	<< 0,001
After 2 years TUD	73	0,72	61,41	<< 0,001
After 3 years TUD	48	0,85	88,72	<< 0,001
After 4 years TUD	38	0,15	2,01	=0,031
After 5 years TUD	26	0,49	7.04	<< 0,001
After 6 years TUD	10	0,90	18,46	<< 0,001
After 7 years TUD	6	0,99	4906	<< 0,001

Conclusions. 1. Testosterone undecanoat 1000 mg injectable i.m. at 3 months does not increase significantly PSA level after 7 years administrations. **2.** PSA level post testosterone was in fact dependent on age, prostatic volume before treatment and the level before treatment.

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