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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<u>Aim</u>. To find if testosterone undecanoat 1000 mg injection (NebidoR; 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 175 patients to whom testosterone undecanoat 1000 mg, i.m. was administrated at 3 months, in the last 4 years, and to whom the prostatic volume was quantified (J.Sex.Med., 2011, 8, suppl. 7: PO-05-013), 106 PSA analysis were done before treatment. PSA was recorded (if possible) at T1 to T7 [2 weeks to 4 years] (see Peretianu, 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: 106 men, 18-96 years, average: 61,95; median: 62.

B. Prostatic volume (cmc): average: 37,89.

C. Average PSA: a. before treatment: 1,76; b. post 1y: 1,9; c. post 2y: 1,68; d. post 3y: 1,94; e. post 4y: 2,18.

	T0	T1- 2 w	T2-3 m	T3 – 6 m	T3 bis – 9 m	T4-1y	T5-2y	T 6 3 y	T7-4y
Average	1,76	2,87	2,45	2,81	2,20	1,90	1,68	1,94	2,18
SD	1,68	3,06	2,54	3,38	3,11	1,78	1,36	1,70	2,20
No	106	14	9	12	10	85	41	30	9
T value vs T0		0.20	0.44	0.31	0.67	0.59	0.76	0.61	0.59

- D. Statistical difference of average: nonsignificant for all the times from 2 weeks to 4 years.
- **E.** Correlation between age and PSA is: 1. significant before (r1) and after treatment after 2 years but nonsignificant for 3 and 4 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 treatment	At 1 year	At 2 years	At 3 years	At 4 years	Before treatment	At 1 year	At 2 years	At 3 years
r	0,34	0,33	0,31	0,15	0,07	0,60	0,49	0,55	0,42
p	<0,001	< 0,01	0,05	>0,1	>0,1	< 0,001	< 0,001	< 0,001	< 0,05

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	\mathbb{R}^2	F	P
1 year TUD	70	0,52	24,03	<< 0,001
After 2 years TUD	38	0,75	34,28	<< 0,001
After 3 years TUD	20	0,89	47,84	<< 0,001
After 4 years TUD	8	0,83	6,5	0,0509

Conclusions.

- 1. Testosterone undecanoat 1000 mg injectable i.m. at 3 months does not increase significantly PSA level after 4 years administrations.
- 2. PSA level post testosterone is in fact dependent on age, prostatic volume before treatment and the level before treatment.