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PROGRAMMAPROSTATA

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Do number of biopsies and PSA doubling time at 3 and 5 years in active surveillance protocols for low-risk prostate cancer associate with upgrading reclassification?

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Objectives

During active surveillance (AS) for low-risk prostate cancer, PSA kinetic and repeat biopsies are key components aimed at detecting reclassification or progression (i.e. histological upgrading to GPS ≥ 7). We evaluated association between PSA doubling time (PSADT), number of performed biopsies and upgrading, in two medium terms windows (3 and 5 years) in an AS cohorts of low risk prostate cancer (PCa) patients (pts).

Patients and Methods

Since 2005, pts were enrolled in the mono-institutional AS protocol, (SA-INT). In November 2007 the international multi-center PRIAS (Prostate Cancer Research International Active Surveillance) protocol was also adopted. Inclusion criteria of the two protocols are shown in the table 1.

	iPSA (ng/ml)	cT	GPS	No of positive cores	Core involvement	PSA density (ng/ml/cc)
SAINT	≤ 10	≤ T2a	≤ 3+3	≤ 25%	≤50%	/
PRIAS	< 10	≤ T2a	≤ 3+3	≤ 2	/	< 0.2

Since 2016, multi-parametric MRI (mpMRI) with target biopsies has eliminated the criterion of the maximum number of positive biopsies.

Monitoring examinations schedules:

•PSA every 3 months (mos)
•DRE every 6 mos
•Biopsy at year 1, 4, 7 in PRIAS protocol;
Biopsy at year 1 and 2, then every 2 years in SAINT protocol.
Very unfavorable PSA DT (VU-PSADT) (i.e. < 3 yrs) originally caused the exit from protocol, while unfavorable PSA DT (U-PSADT) between 3 and 10 years provided extrabiopsy (XBx). Actually, any PSA DT < 10 years is discussed for XBx, while favorable PSADT (F-PSADT) does not provide XBx.

Triggers for treatment:

•GPS> 3+3 - Grade Group > 1
•Positive cores > 25% total cores in SAINT, >2 in PRIAS, until mpMRI introduction in 2016.

Results

From March 2005 to October 2018, 1036 pts were included in AS, 338 in SAINT and 698 in PRIAS protocols. We evaluated the proportion of biopsies with upgrading (UG) according to PSADT (VU-PSADT, U-PSADT and F-PSADT) and no. of repeat biopsies at 3 and 5 yrs. Chi-square test was performed.

In the 3rd yr window (36 ± 6 months), 117 pts underwent biopsy: 43 (38.1%) with F-PSADT, 64 (56.6%) with U-PSADT and 6 (5.3%) with VU-PSADT, 4 had not evaluable PSADT.
In 5th yr window (60 ± 6 mos) 45 pts underwent biopsy: 22 (51.2%) having F-PSADT and 21 (48.8%) having U-PSADT, none had VU-PSADT, 2 had not evaluable PSADT.
Table 2 and 3 show UG detection rate, according to PSADT and according to the number of repeat biopsies, respectively, in the selected time windows.
All pts receiving a reclassified pathology had undergone 2 or 3 repeat biopsies, considering both the 3 and 5 years intervals (tab. 3).
Neither PSA-DT (p=0.10) nor no. of biopsies (p=0.54) were significantly associated with UG during 3rd yr. During 5th year, PSADT showed a slight association with UG (p=0.035), while no. of biopsies did not (p= 0.332).

	F-PSADT (>10 ys)	U-PSADT (3-10 ys)	VU-PSADT (<3 ys)
3 ys	6/43 (13.9%)	12/64 (18.8%)	3/6 (50%)
5 ys	in 1/22 (4.6%)	6/21 (28.6%)	0

Table 2: upgrading detection rate according to PSA-DT

	No repeat biopsies				
	1	2	3	4	5
3 ys	0/5	17/79 (21.5%)	4/28 (14.3%)	0/1	
5 ys	0/1	1/5 (20%)	6/23 (26%)	0/13	0/1

Table 3: upgrading detection rate, according to number of repeat biopsies

Conclusions

Proportions of UG were comparable in 3rd (18%) and in 5th (16%) year. No patient had VU-PSADT at the 5th year. No. of biopsies did not associate with different proportion of UG in both windows, but all of those who had reclassified disease had 2 or 3 repeat biopsies. PSA-DT did not associate with UG at 3 year (few cases in VU-PSADT) but U-PSA-DT group showed a trend at 5 year. Possibly, PSA-DT in the middle term (5 years) may become a more stable predictor of tumor behavior and may be useful in indicating an extra-biopsy during AS.