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NADiA ProsVue: A prognostic test for identifying men at a reduced risk for prostate cancer recurrence following radical prostatectomy

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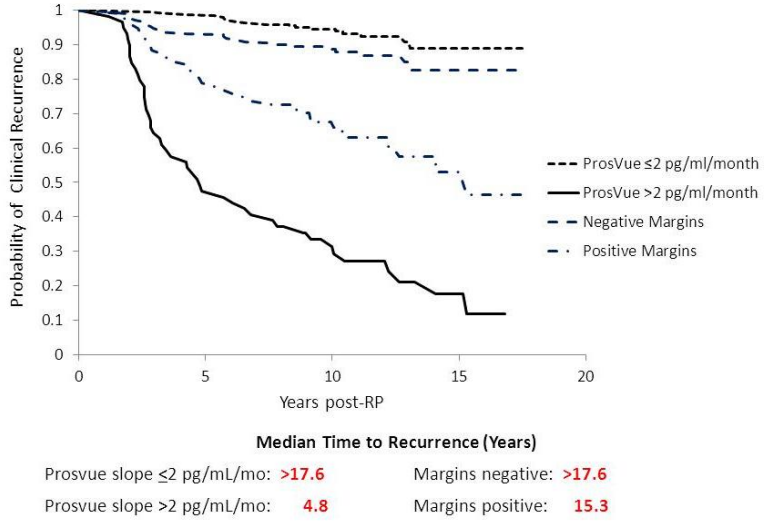
Introduction: Clinical recurrence after radical prostatectomy (RP) is difficult to predict since established factors do not reliably stratify risk. We validated a pre-specified hypothesis that a post-RP NADiA® PSA slope cutpoint of ≤2.0 pg/mL/month (mo) identifies men at reduced risk of clinical recurrence as determined by positive biopsy, imaging or prostate cancer death. This study aimed to compare the prognostic strength of the ProsVue slope cutpoint vs. surgical margin status to identify men at very low risk of post-RP clinical recurrence.

Methods: From a cohort of 304 men, surgical margin data was available for 234 men. PSA was measured with a Nucleic Acid Detection Immunoassay (NADiA®) having a limit of quantification of 0.00065 ng (0.65 pg) per mL. Least-squares linear PSA slope (ProsVue™) was calculated using 3 serum samples drawn 1.5-20 mo post-RP. Recurrence risk using a 2.0 pg/mL/mo ProsVue cutpoint and surgical margin status were compared by two survival methods, univariate Cox proportional hazards regression analysis (table) and Kaplan-Meier plots (figure).

Results: ProsVue slope ≤2.0 pg/mL/mo was significantly associated with a reduced risk of clinical recurrence by univariate Cox analysis (HR 18.3, 95% CI, 10.6–31.8, P < 0.0001). A negative surgical margin was less significantly associated with a reduced risk of recurrence (HR 3.3, 95% CI 2.0–5.4). Median time to recurrence for men with ProsVue slope ≤2.0 pg/mL/mo and those with negative margins exceeded 17.6 years (yrs). However, median time to recurrence in men with ProsVue slope >2.0 pg/mL/mo was shorter compared to those with positive margins.

Variables	N	Median f/u (yrs)	No. (%) Recurred	Univariate HR (95% CI)	P value
ProsVue slope					
≤2.0 pg/mL/mo	245	10.6	18 (7.3)	1.0	<0.0001
>2.0 pg/mL/mo	59	7.8	46 (78.0)	18.3 (10.6 – 31.8)	
Surgical margins					
Negative	139	10.5	27 (19.4)	1.0	<0.0001
Positive	95	9.9	36 (37.9)	3.3 (2.0 – 5.4)	

Table



Figure

Conclusions: ProsVue slope ≤2.0 pg/mL/mo was found to be a stronger risk identifier for clinical recurrence of prostate cancer in men following RP than surgical margin status.