

1847
[-2]PROPSA IN COMBINATION WITH PSA AND FREE-PSA, USING THE BECKMAN COULTER ACCESS IMMUNOASSAY SYSTEMS IMPROVES PROSTATE CANCER DETECTION RELATIVE TO PSA AND FREE PSA. A MULTI-CENTER PROSPECTIVE CLINICAL STUDY.

*William J Catalona**, Chicago, IL; *Martin G Sanda*, Boston, MA; *John T Wei*, Ann Arbor, MI; *George G Klee*, Rochester, MN; *Kevin M Slawin*, Houston, TX; *Leondard S Marks*, Los Angeles, CA; *Chris H Bangma*, Rotterdam, Netherlands; *Daniel W Chan*, Lori J Sokoll, Baltimore, MD; *William L Roberts*, Salt Lake City, UT; *Ron van Schaik*, Rotterdam, Netherlands; *Dennis L Broyles*, Amabelle B Cruz, Isaac A Mizrahi, Sanghyuk S Shin, Carlsbad, CA; *Alan W Partin*, Baltimore, MD

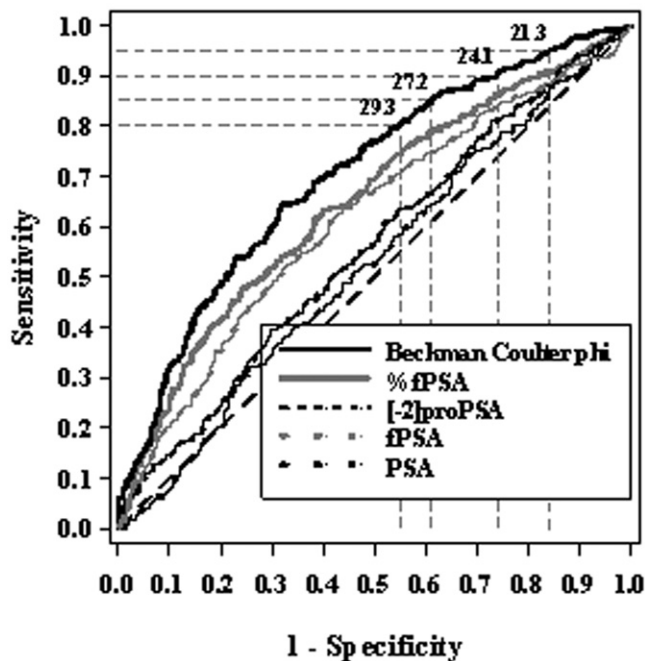
INTRODUCTION AND OBJECTIVES: The limited clinical specificity of PSA and %fPSA has been a long-term issue when using these markers for prostate cancer (PCa) detection. This study was aimed at evaluating the use of [-2]proPSA, a fPSA isoform, in a multi-center, prospective clinical trial.

METHODS: 892 subjects (430 PCa and 462 benign by biopsy) with PSA from 2-10 ng/mL were enrolled from 7 clinical centers. Subjects were > 50 years of age, with non-suspicious DRE. 97% of subjects were prospectively collected and 98% had > 10 core biopsies. [-2]proPSA, PSA and fPSA were analyzed on the Beckman Coulter Access 2 Immunoassay Analyzer. We compared the utility of PSA, %fPSA and a formula combining PSA, fPSA, and [-2]proPSA (Beckman Coulter Prostate Health Index or phi***) to assess PCa risk.

RESULTS: phi significantly improved the clinical specificity relative to %fPSA for PCa detection. At 95% sensitivity the specificity of phi was about 2-fold higher than %fPSA. ROC analyses (Figure) for PSA, fPSA, [-2]proPSA, %fPSA, and phi resulted in areas under the curve (AUC) of 0.525, 0.615, 0.557, 0.648, and 0.703, respectively (all with p < 0.003 relative to chance alone except PSA with p = 0.199). A significant relationship was found between phi and the relative risk of PCa in individual men, with higher phi values indicating higher risk of PCa (Table). The probability of PCa ranged from 11% for phi values < 25 to 52% for phi values ≥ 55.

CONCLUSIONS: The use of phi significantly increased the specificity compared to %fPSA for PCa detection in men with PSA levels of 2-10 ng/mL and non-suspicious DRE. A strong relationship between phi and probability of PCa was also demonstrated. We conclude that phi may add significant information regarding individual patient risk and may be used as an aid in patient management.

**Not intended as off-label promotion of any BCI product.
 ***Pending FDA approval.



Beckman Coulter phi Range	Probability of Cancer (95% Confidence Interval)	Relative Risk (95% Confidence Interval)	Percent of patients in phi range
0-24.9	11.0% (6.5% - 15.8%)	1.0	24.9%
25.0-34.9	18.1% (13.7% - 22.6%)	1.6 (1.0 - 3.1)	32.8%
35.0-54.9	32.7% (27.3% - 38.0%)	3.0 (1.9 - 5.3)	29.5%
55.0+	52.1% (42.0% - 62.1%)	4.7 (3.0 - 8.3)	12.8%

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1848
THE ACCURACY OF THE PERCENTAGE OF POSITIVE CORES IN PREDICTING ADVANCED PROSTATE CANCER DOES NOT CHANGE ACCORDING TO THE EXTENT OF BIOPSY SCHEME

*Firas Abdollah**, Alberto Briganti, Umberto Capitanio, Vincenzo Scattoni, Marco Roscigno, Roberto Bertini, Renzo Colombo, Dario Di Trapani, Massimo Freschi, Andrea Cestari, Giorgio Guazzoni, Patrizio Rigatti, Francesco Montorsi, Milan, Italy

INTRODUCTION AND OBJECTIVES: Previous studies have shown that percentage of positive cores (PPC) represents a significant predictor of advanced prostate cancer (PCa) at radical prostatectomy (RP). However, the accuracy of PPC in predicting non-organ confined disease according to the extent of biopsy scheme has not been addressed yet. The aim of this study was to evaluate the accuracy of PPC in predicting unfavourable pathological outcomes according to different prostate biopsy schemes.

METHODS: We evaluated a cohort of 470 consecutive patients undergoing prostate biopsy and subsequent RP for clinically localized prostate cancer between January 2006 and August 2009 at a single tertiary referral center. We divided all patients according to the number of biopsy cores taken: group 1 (extended biopsy: 10-19 cores) and group 2 (saturation biopsy: ≥20 cores). The accuracy of PPC (defined as the number of positive cores over the number of total cores taken) in predicting the presence of advanced PCa (defined as pT3/pT4 disease and/or lymph nodes invasion) was assessed with AUC estimates. The same analyses were repeated separately in each group. Moreover, the predictive accuracy (PA) of a multivariate model includ-