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### APPROPRIATE PATIENT SELECTION FOR FOCAL THERAPY OF PROSTATE CANCER: THE ROLE OF TRANSPERINEAL 3-DIMENSIONAL MAPPING OF THE PROSTATE- AN 8-YEAR EXPERIENCE.

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**INTRODUCTION AND OBJECTIVES:** While a select group of patients with prostate cancer may benefit from focal or partial gland ablation, validated criteria for patient selection do not exist. We evaluated the utility of template guided transperineal 3-dimensional pathologic mapping (3-DPM) biopsies with concomitant transrectal ultrasound (TRUS) guided biopsies in selecting patients who appeared suitable for focal therapy (FT) based on initial office TRUS biopsy.

**METHODS:** Between 2001 and 2009, a total of 140 patients with unilateral positive disease based on an initial TRUS biopsy underwent 3-DPM biopsies in conjunction with repeat TRUS biopsies, as part of a re-staging evaluation for active surveillance or focal hemi-gland cryoablation. Patients were considered eligible for FT if after re-staging: A) there was no cancer on the side contralateral to the presenting lesion on initial TRUS biopsy; or B) and C) if the extent of cancer on the contralateral side was consistent with modified definitions of indolent criteria: B) Gleason  $\leq 6$  and maximal cancer length  $\leq 2$ mm in any core (Goto et al.1995); and C) Gleason  $\leq 6$  and  $\leq 25\%$  of total cores positive, with  $\leq 50\%$  involvement in a single core (Epstein et al. 1994). The result of 3-DPM were compared to the repeat TRUS biopsies in determining patient suitability for focal cryoablation which served as the end point for this study

**RESULTS:** Median age was 71 years, median PSA 5.3 ng/mL, mean prostate volume of 43.8 cc, and a median of 84 cores were obtained, yielding a mean of 2.01 cores per cc of prostate volume. Of the 140 patients 67(48%), 102(73%), and 108(77%) were deemed suitable for FT using suitability definitions A, B and C respectively. While all 140 patients had a 3-DPM only 125 had a concomitant repeat TRUS. When comparing 3-DPM to repeat TRUS in determining suitability for FT using definition A, 66/125 ( 53%) were unsuitable by 3-DPM while 8/125(6.4%) were unsuitable by TRUS. Repeat TRUS biopsies had a false negative rate of 52%, a sensitivity of 34%, and a negative predictive value of 28%.

**CONCLUSIONS:** In patients presenting with unilateral disease based on initial TRUS biopsy, only 48% were deemed suitable for focal hemi-gland ablation following 3-DPM using strict eligibility criteria. Concomitant repeat TRUS biopsy did not appear to add to the information obtained by 3-DPM alone. We believe that transperineal 3-DPM is an appropriate re-staging procedure that can exclude patients whose cancer is outside the region destined to be treated while precisely locating the targeted area(s) to be selectively ablated

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### EVALUATION OF [-2]PROPSA IN COMBINATION WITH PSA AND FREE PSA, USING THE BECKMAN COULTER ACCESS IMMUNOASSAY SYSTEMS, FOR IDENTIFYING PATIENTS WITH AGGRESSIVE PROSTATE CANCER. A MULTI-CENTER PROSPECTIVE CLINICAL EVALUATION.

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**INTRODUCTION AND OBJECTIVES:** [-2]proPSA, an isoform of fPSA, in combination with PSA and fPSA, has been shown to enhance prostate cancer (PCa) detection. For patients with PCa,

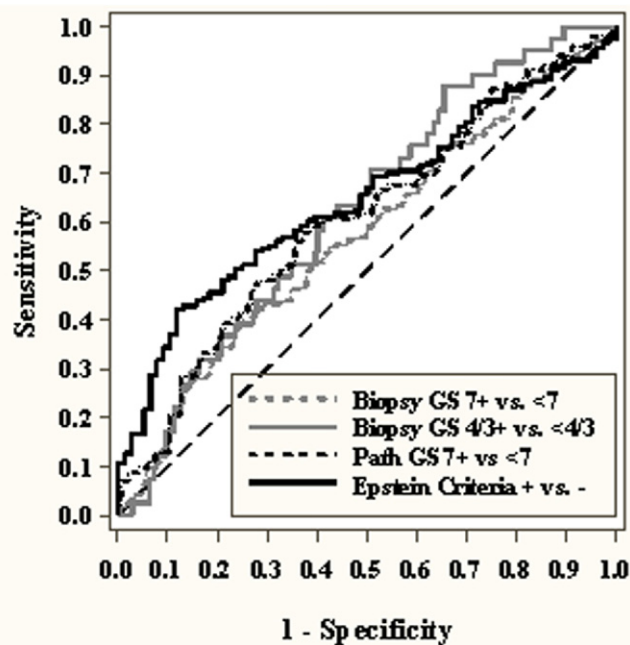
markers that could identify aggressive cancer would be an important adjunct in guiding therapy. This study evaluated the use of these three markers in identifying subjects with aggressive cancer defined by Gleason score and the Epstein criteria.

**METHODS:** 430 subjects with PCa were identified at 7 clinical centers. Subjects were 50 to 84 years of age, with PSA values between 2-10 ng/mL and non-suspicious DRE. [-2]proPSA, PSA, and fPSA were analyzed on the Beckman Coulter Access 2 Immunoassay Analyzer and the utility of these markers in a formula called Beckman Coulter Prostate Health Index (phi\*\*\*) was evaluated to see if phi could identify subjects with aggressive PCa based on biopsy Gleason score (N=139, Gleason score  $\geq 7$ ; N=290, Gleason score  $< 7$ ) or pathologic Gleason score (N=135, GS  $\geq 7$ ; N=102, GS  $< 7$ ) or the Epstein criteria (N=76, aggressive; N=264, non-aggressive).

**RESULTS:** The relationship between phi and biopsy Gleason score was statistically significant ( $r=0.138$ ,  $p=0.004$ ). A trend correlating higher phi values with higher prostatectomy Gleason scores was also noted. In this study population, the % of subjects with  $GS \geq 7$  increased from 26.2% to 28.2% to 30.1% and to 42.1% for subjects with phi values between 0-24.9, 25.0-34.9, 35.0-54.9 and  $\geq 55$ , respectively. The relative risk of high grade cancer, compared to phi  $< 25$ , increased from 1.0, 1.08, 1.15, and 1.61 for the four phi ranges ( $p=0.0131$  using Cochran-Armitage Test for Trend). Based on ROC analyses with phi (Figure), the AUCs using Epstein criteria, biopsy Gleason score  $\geq 4+3$  vs.  $<3+4$ , pathologic Gleason score  $\geq 7$  vs.  $<7$ , and biopsy Gleason score  $\geq 7$  vs.  $<7$  were 0.6467, 0.6062, 0.6236, and 0.5729, respectively.

**CONCLUSIONS:** The ROC and relative risk analyses using phi suggest that higher phi values are associated with more aggressive cancer when defined by the Epstein criteria or Gleason score. These observations need to be validated in future studies.

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



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