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USE OF HUMAN KALLIKREIN-2 (HK2) LEVELS IN PATIENT SELECTION FOR PROSTATE BIOPSY Robert K. Nam*, Steven A. Narod, John Trachtenberg, Angeliki Magklara, Eleftherios P. Diamandis, Michael A.S. Jewett. Toronto, Canada

Introduction and Objectives: Serum hK2 levels are positively associated with the presence of prostate cancer, independent of serum PSA level and DRE. We hypothesize that serum hK2 levels can more accurately identify PSA and DRE prescreened patients who should undergo prostate biopsy.

Methods: We conducted a case-control study of 1059 men with no history of prostate cancer and who were referred for prostate biopsy from 1997-1999. PSA and hK2 levels were measured using specific non-isotopic immunometric techniques. Cases were patients who were diagnosed with adenocarcinoma of the prostate from biopsy, and controls were patients who had no evidence of cancer from biopsy. The odds ratio for detection of prostate cancer was determined for hK2 measurements, adjusting for age, race, PSA, DRE, family history of prostate cancer, and urinary obstructive symptoms. hK2 cut-off levels were tested to determine how it would alter pre-test probabilities for cancer detection with receiver operator characteristics curves.

Results: Of the 1059 men, 476 (45.0%) had cancer. A subset of 318 men underwent a repeat prostate biopsy because of an initial negative result, and 101 (31.8%) were found to have cancer. The mean hK2 levels were significantly higher in the cases than in the controls (0.73 vs. 0.28 ng/mL, $p < 0.0001$). The crude and adjusted odds ratio for prostate cancer detection for patients in the highest quartile of hK2 level was 3.5 (95% C.I.: 2.4-5.0, $p < 0.0001$) and 2.9 (95% C.I.: 1.8-4.5, $p < 0.0001$), respectively, compared to patients in the lowest quartile. Among patients at low risk for prostate cancer (PSA level of less than 10 ng/mL and absence of prostatic nodule), the hK2 level was able to increase the pre-test probability for cancer from 37% to 51% ($p = 0.001$) based on an optimal cut-off value of 0.40 ng/mL. Also, for the 318 men who underwent a repeat biopsy, mean hK2 levels were significantly higher in cases than in controls (0.55 vs. 0.37 ng/mL, $p = 0.01$).

Conclusions: High serum hK2 level is an independent risk factor for prostate cancer. It may improve the predictive value for patients with low pre-test probabilities for prostate cancer based on PSA and DRE. It may also determine which patients should undergo repeat prostate biopsy after an initial negative biopsy result.