THE 4KSCORE TEST PREDICTS UPGRADING IN PROSTATECTOMY SPECIMEN AMONG MEN WITH LOW-GRADE PROSTATE CANCER ON PROSTATE BIOPSY

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INTRODUCTION

Most men diagnosed with prostate cancer (PCa) in the United States are found to have low-grade tumors. While many of these men are candidates for active surveillance, a proportion may have a bad outcome owing to aggressive prostate cancer that was missed on initial biopsy. A recent prospective study confirmed the 4Kscore® Test accurately predicts the likelihood of aggressive cancer on prostate biopsy.

OBJECTIVE

The purpose of this study was to see if the 4Kscore could predict the presence of Gleason ≥7 in the prostatectomy specimen in a cohort of men with low-grade tumors on prostate biopsy who underwent radical prostatectomy (RP).

METHODS

➢ Multi-center prospective trial among 26 urological sites from Oct 2013 – Apr 2014
➢ Men referred for biopsy of the prostate based on clinical suspicion of prostate cancer, regardless of age, DRE findings and prior biopsy status
➢ 4Kscore blood test consists of levels of 4 kallikrein proteins (total PSA, free PSA, intact PSA, and hK2) combined with DRE findings, and prior biopsy status
➢ The primary outcome of this study was to identify Gleason ≥7 prostate cancer on prostate biopsy
➢ Analysis performed on a subgroup of men who were found to have low-grade (Gleason 6) cancer on biopsy and underwent RP

RESULTS

➢ 144 of 1312 men enrolled in the study were found to have prostate cancer and underwent radical prostatectomy
➢ 50 of 144 men had Gleason 6 cancer on prostate biopsy, Results on RP:
  ➢ 21 (42%) men had Gleason ≤6 PCa
  ➢ 26 (52%) men had Gleason 7 PCa
  ➢ 2 (4%) men had Gleason ≥8 PCa
  ➢ 1 (2%) man had no cancer at RP
➢ Using a 4Kscore cut off of 7.5%, tumor upgrading occurred in 35% (6/17) men with a 4Kscore < 7.5% vs. 67% (22/33) men with a 4Kscore ≥ 7.5%
➢ For a 4Kscore ≥ 20%, tumor upgrading occurred in 85% (11/13) men
➢ A high risk 4Kscore is positively associated with the risk of Gleason upgrade at RP (p=0.030)

CONCLUSIONS

In a subset of men who had Gleason 6 disease on biopsy and underwent RP, higher 4Kscores were associated with disease upgrading in surgical specimen. Men with 4Kscores ≥ 20% and Gleason 6 prostate cancer on biopsy have the highest likelihood of harboring Gleason ≥7 disease and as such these men may not be suitable candidates for active surveillance protocols.