



The Impact of Clinical CCP Testing in Men with Localized Prostate Cancer for Expanding the Population of Men Eligible for Active Surveillance

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Disclosures

S. Stone, R. Bernhisel, and M. Brawer are employees of Myriad Genetics, Inc. and receive salary and stock options.

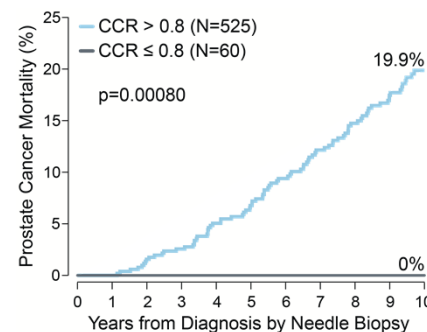
Introduction

- Active surveillance (AS) is an established treatment modality for select men with prostate cancer, but robust selection of appropriate patients is lacking.
- A validated cell-cycle progression risk (CCR) score provides significant prognostic discrimination to newly diagnosed prostate cancers by combining:
 - **Molecular risk:** Cell-Cycle Progression (CCP) Score
 - **Clinical risk:** CAPRA

Cohort and Molecular Testing

- 17,017 men were submitted by their physicians for CCP testing (Myriad Genetic Laboratories).
 - Gene expression of 31 CCP genes and 15 housekeeping genes
 - The CCR Score combines the CCP score with CAPRA.
- Clinicopathological data was obtained from physician-completed test request forms.

CCR Threshold Score Validation



- Training Cohort N=505
- Validation Cohort N=585

Mean Risk of 10-year PCM for CCR ≤ 0.8: 1.9%

Analysis

- We evaluated the proportion of men eligible for AS based on their CCR score (≤ 0.8), including those whose clinicopathologic criteria would traditionally **disqualify** them from AS.
 - PSA > 10ng/mL
 - Gleason grade group ≥ 2 (Gleason score 3+4)
 - AUA intermediate risk or high risk

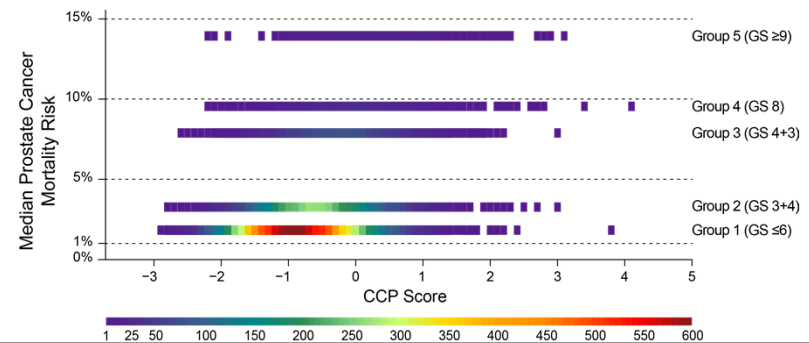
AUA Risk Category

Characteristic	Categories	Tested Men N	Qualify for AS Based on CCR N (%)
Total		17,017	11,339 (66.6%)
AUA risk classification	Low risk	9,135	8,446 (92.5%)
	Intermediate risk	6,183	2,653 (42.9%)
	High risk	1,699	240 (14.1%)

PSA in Gleason Grade Group 1 (GS≤6)

Characteristic	Categories	Tested Men N	Qualify for AS Based on CCR N (%)
Total		10,211	9,103 (89.1%)
PSA (ng/mL)	≤ 10	9,481	8,752 (92.3%)
	> 10	730	351 (48.1%)

CCP Scores by Gleason Grade Group



Gleason Grade Group

Characteristic	Categories	Tested Men N	Qualify for AS Based on CCR N (%)
Total		17,017	11,339 (66.6%)
Gleason Grade Group	1 (Gleason ≤ 6)	10,211	9,103 (89.1%)
	2 (Gleason 3+4)	4,460	2,177 (48.8%)
	3 (Gleason 4+3)	1,449	42 (2.9%)
	4 (Gleason 8)	585	14 (2.4%)
	5 (Gleason ≥ 9)	312	3 (1.0%)

Conclusions

- A significant proportion of men who qualify for AS based on their CCR score have clinicopathologic features that may traditionally disqualify them for AS.
- This shows that the CCR score threshold increases the number of men identified as candidates for AS.

