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Clinical Utility of CCP Test in Personalizing Prostate Cancer Treatment

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Background

- The purpose of the cell cycle progression (CCP) test is to *enhance physician-patient decision making* in personalizing prostate cancer treatment after a diagnostic biopsy.
- The CCP test is a validated molecular assay that assesses risk of prostate cancer–specific disease progression and mortality.¹⁻⁶
- This was a *prospective clinical utility* study of 1,206 patients conducted for MoDx/Medicare coverage determination.

1. Cuzick J, et al. *Lancet Oncol.* 2011;12(3):245-255.

2. Cuzick J, et al. *Br. J. Cancer.* 2012;106(6):1095-1099.

3. Cooperberg MR, et al. *J Clin Oncol.* 2013;31(11):1428-1434.

4. Freedland SJ, et al. *Int J Radiat Oncol Biol Phys.* 2013;86(5):848-853.

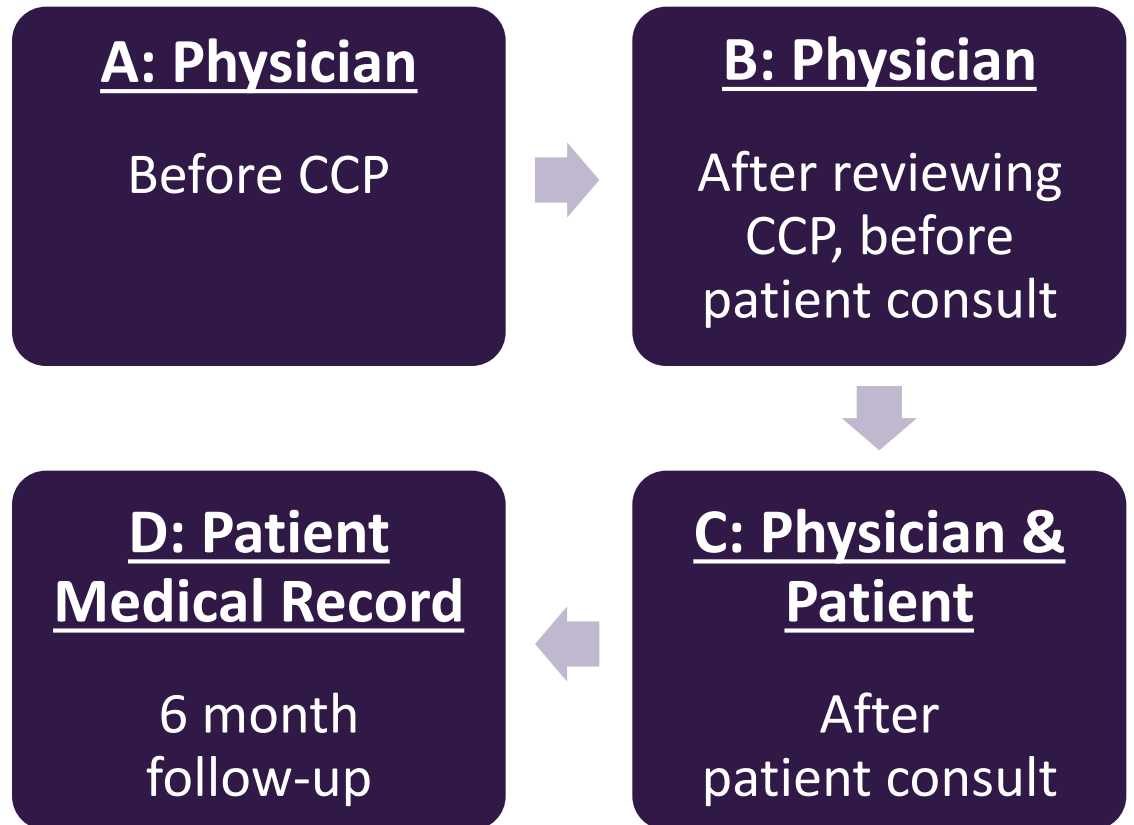
5. Bishoff JT, et al. *J Urol.* 2014;192(2):409-414.

6. Crawford ED, et al. *Curr Med Res Opin.* 2014;30(6):1025-1031.

Methods

- Untreated patients with newly diagnosed (≤ 6 months), clinically localized prostate adenocarcinoma were enrolled; 60.3% within the month of diagnosis.

- 4 sequential surveys to track changes in treatment decisions.



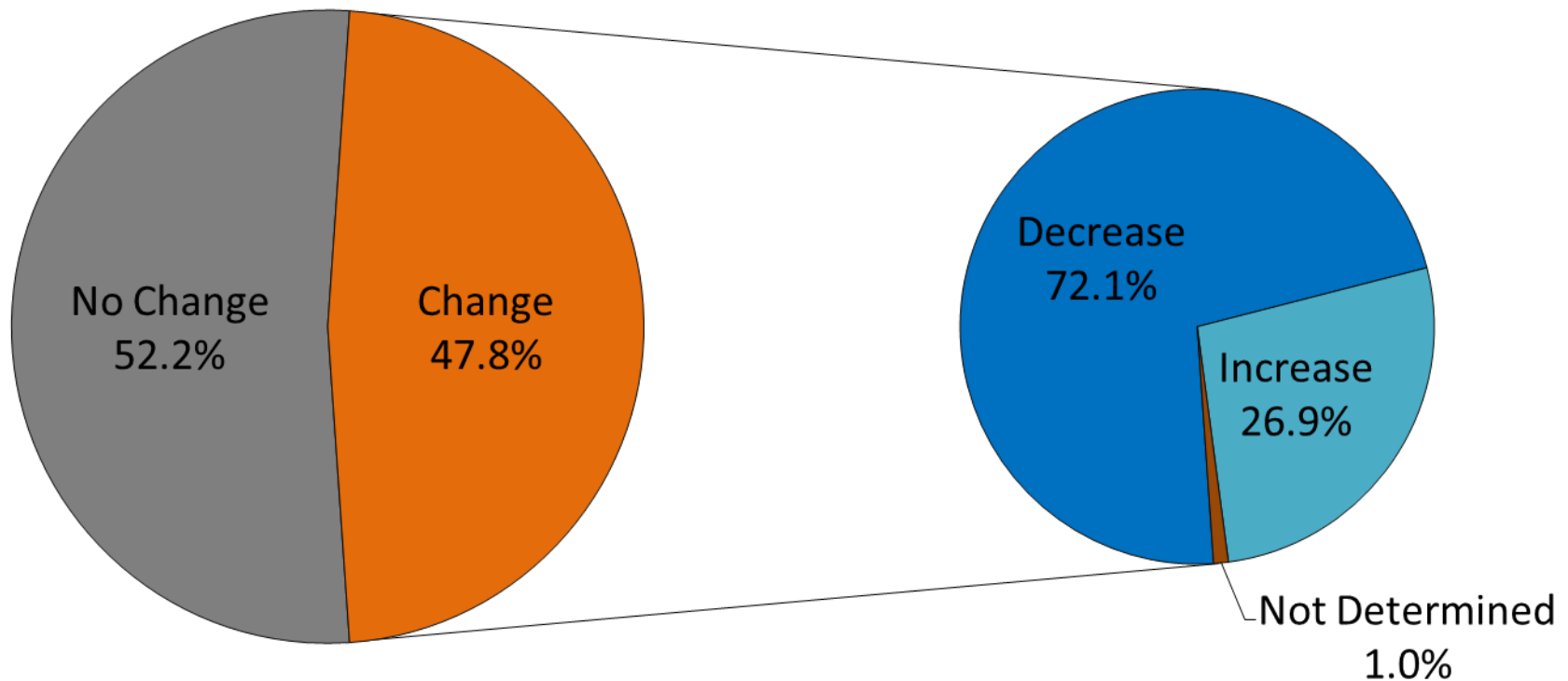
Patient Demographics and Baseline Characteristics

Characteristic Variable	Statistic/ Category	All Patients (N = 1206)
Age (yrs.)	Mean	65.9
Clinical Stage	T1	892
	T2	301
	T3	13
% Positive Cores	Mean	33.2
Pre-Biopsy PSA Categorized	0 - 4.0	177 (14.7%)
	4.1 - 10	820 (68.0%)
	>10	209 (17.3%)
Gleason Score	6	577 (47.8%)
	7 (3 + 4)	337 (27.9%)
	7 (4 + 3)	143 (11.9%)
	8	100 (8.3%)
	≥ 9	49 (4.1%)
AUA Risk	Low	486 (40.3%)
	Intermediate	506 (42.0%)
	High	214 (17.7%)

Characteristic Variable	Statistic/ Category	All Patients (N = 1206)
CCP Score	Mean	-0.7
10-year mortality risk (%)	Mean	4.2
Race	Caucasian	928 (77.0%)
	Latino/Hispanic	110 (9.1%)
	African	107 (8.9%)
	Other	61 (5.1%)
Charlson Comorbidity Index	0	863 (71.6%)
	1	212 (17.6%)
	2	68 (5.6%)
	3	42 (3.5%)
	4	9 (0.7%)
	≥ 5	12 (1.0%)

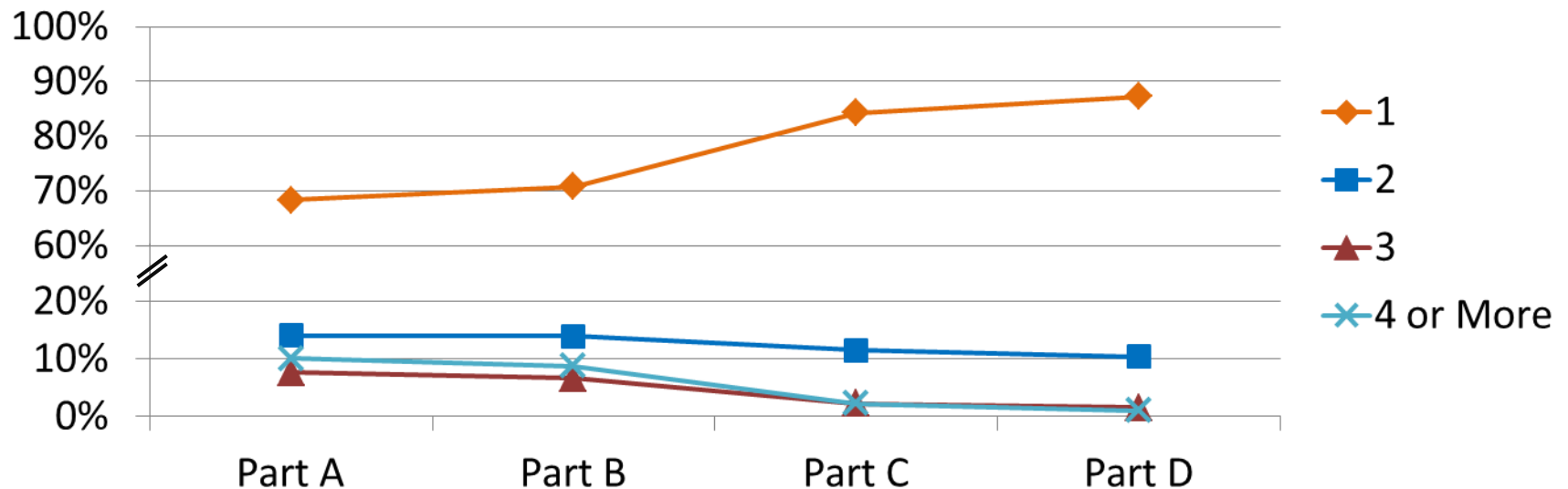
CCP Test Causes Changes in Treatment

- The CCP score caused a change in actual treatment administered in 47.8% of patients.



Changes in Number of Treatments Assigned

- There was a strong statistically significant trend towards reduction in the number of treatments assigned/administered per patient, particularly from Part B to C.



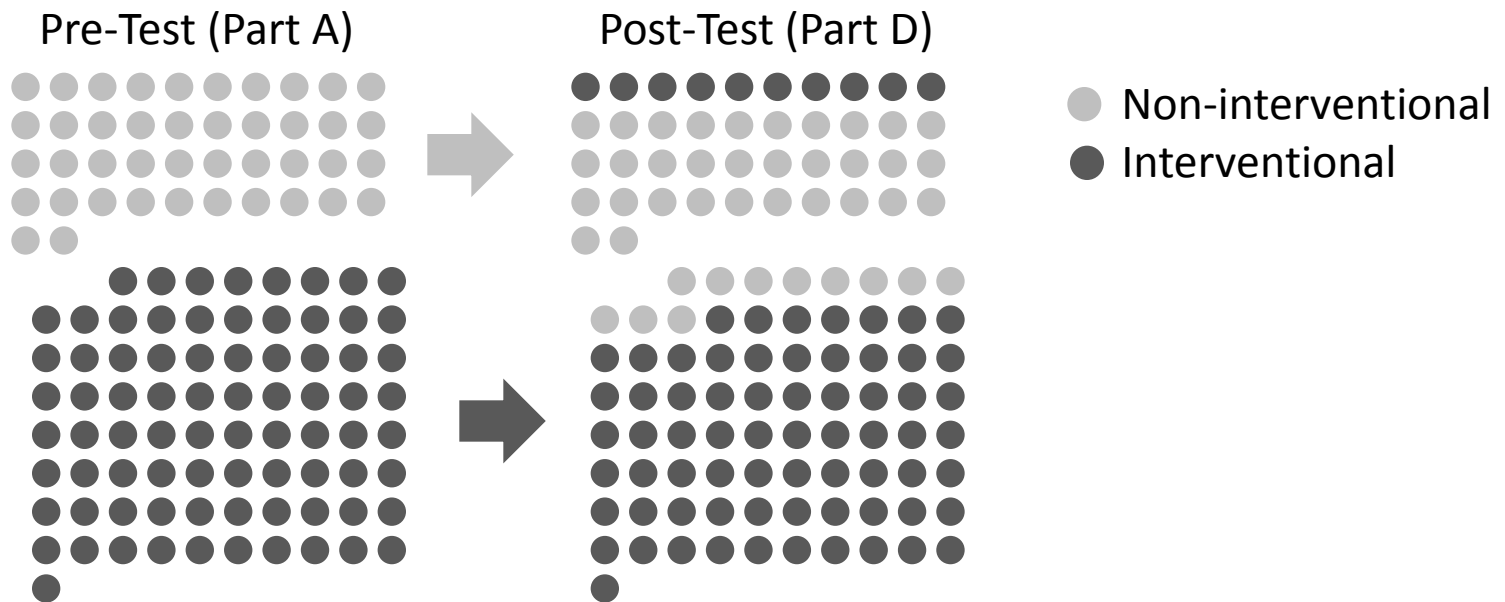
	Part A (Pre-CCP)	Part B	Part C	Part D (6 mo. follow-up)
Weighted Mean	1.72	1.64	1.24	1.16
CMH χ^2 p-value <0.0001				

Changes in Individual Treatment Options

Modality/Treatment	# Patients Recommended Pre-CCP	# Patients Administered Post CCP	Percent Change
Non-Interventional	417	428	+2.6%
Interventional	789	778	-1.4%
High Intensity Focused Ultrasound	30	2	-93.3%
Proton Beam Radiation	24	5	-79.2%
Cryosurgery	94	33	-64.9%
Brachytherapy – High Dose Rate	112	42	-62.5%
CyberKnife	18	8	-55.6%
EBRT Adjuvant	60	27	-55.0%
ADT - Concurrent	54	27	-50.0%
Brachytherapy - Interstitial	205	111	-45.9%
EBRT Primary	389	239	-38.6%
PLND	27	17	-37.0%
Radical Prostatectomy	479	316	-34.0%
ADT - Neoadjuvant	81	57	-29.6%
ADT - Adjuvant	49	50	+2.0%
ADT - Primary	28	29	+3.6%
Other	10	12	+20.0%

Overall Changes in Treatment

Part A Treatment Modality	Part D Treatment Modality		
	Non-Interventional	Interventional	Totals
Non-Interventional (34.6%)	316 (75.8%)	101 (24.2%)	417
Interventional (65.4%)	112 (14.2%)	677 (85.8%)	789
Totals	428	778	1206



*Each dot represents 10 patients

Conclusions

- The CCP test significantly influenced joint decision making towards appropriate personalized treatment.
- The CCP test caused a change in treatment for nearly half of the patients in this study, 3/4^{ths} of whom had decreased treatment assignments.
- For patients that were initially assigned to interventional treatment, the number of treatments administered per patient decreased after patient and physician review.
- This study shows that the CCP test allows improved and more precise prognostic characterization of patients for appropriate treatment selection.