SIGNIFICANT REDUCTION IN THERAPEUTIC BURDEN FROM USE OF CCP TEST IN TREATMENT DECISIONS AMONG NEWLY DIAGNOSED PROSTATE CANCER PATIENTS IN A LARGE PROSPECTIVE REGISTRY

Brian Willard, MD¹; Todd Cohen, MD¹; Neal Shore, MD²; Judd Boczko, MD³; Naveen Kella, MD⁴; Brian J Moran, MD⁵; Fernando J Bianco MD,⁶; E David Crawford, MD⁷; Rajesh Kaldate MS,⁶; Michael K Brawer, MD⁶; Mark L Gonzalgo MD, PhD⁶

1. Carolina Urology Partners, Lexington, SC 2. Carolina Urologic Research Center, Myrtle Beach, SC 3. WESTMED Medical Group, Woodmere, NY 4. The Urology and Prostate Institute, San Antonio, TX 5. Prostate Cancer Foundation of Chicago, Westmont, IL 6. Urological Research Network, Miami Lakes, FL 7. University of Colorado at Denver, Aurora, CO 8. Myriad Genetic Laboratories, Inc., Salt Lake City, UT 9. University of Miami Miller School of Medicine, Miami, FL

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
- PROCEDE-1000 was a prospective clinical utility study of 1,206 patients to evaluate the impact of the CCP test towards personalizing prostate cancer treatment.
- Results of the full study as well as a subset analysis of 119 patients from Carolina Urology Partners are presented.

METHODS

Figure 1. Study Schema

Physician IDs

Eligible Patients

Physician Completes Part A-

Initial Treatment Plan

CCP Test Run on

Patient Biopsy

CCP Test Results Returned

to Physician

Pysician Completes Part B-

Intended Treatment

Physician Completes Part C-

Agreed Upon Treatment

nysician Completes Part D-

Actual Treatment

Physician Questionnaires

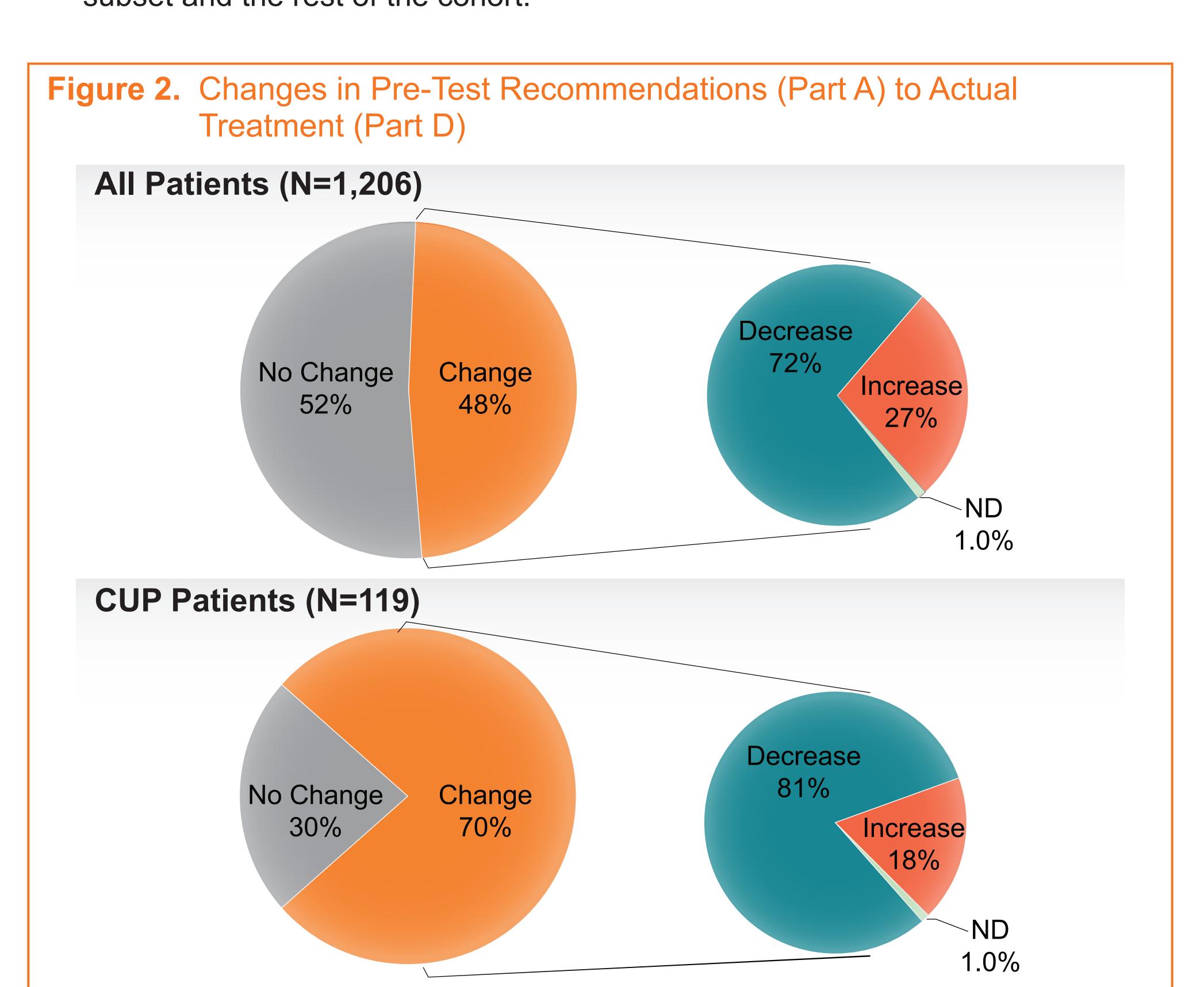
- Untreated patients with newly diagnosed (≤6 months), clinically localized prostate adenocarcinoma were enrolled.
- The physician's initial therapy recommendation (pre-CCP), based on clinicopathologic parameters, was recorded on the first questionnaire (Part A).
- The CCP test was then conducted on prostate biopsy tissue.
- Three consecutive post-CCP questionnaires recorded the physician's revised and actual treatment (see Figure 1).
- Changes in treatments between the initial recommendation and post-CCP questionnaires demonstrate the impact of CCP testing on treatment decision at each stage.
- Various statistical tests were conducted to compare the 119 CUP Urology patients with the remaining 1107 patients, across different clinical characteristics and utility measures.

Description of Cohort

- For the overall cohort, questionnaires were completed for 1206 individuals by 124 physicians from 24 states.
- For the CUP subset analysis, questionnaires were completed for 119 individuals treated at Carolina Urology Partners (CUP).
- CUP is a large community practice consisting of 34 physicians at 15 offices throughout North and South Carolina.

Patient demographic and baseline characteristics are shown in Table 1, for both the full cohort and the CUP subset.

- Table 2 shows that there was a significant reduction in the treatment burden for patients in the CUP subset for each successive evaluation (p < 0.001).
 - The mean number of treatments per patient decreased from 2.66 pre-CCP test to 1.19 in actual follow-up.
 - This reduction is comparable to what was observed for the overall cohort.
- From pre-CCP therapy recommendation, the CCP risk score caused a change in actual treatment administered in 70% of the patients in the CUP subset.
 - 81% were reductions in treatment (Figure 2).
- Table 3 compares the changes in treatment modality for the CUP subset with the cohort as a whole.
 - 31.1% (37/119) of men in the CUP subset received conservative treatment.
- These results support and mirror the data obtained from the entire patient cohort. No statistically significant difference was observed between the CUP subset and the rest of the cohort.



RESULTS

Table 1. Patient D	emographics	and Baseline Cl	haracteristics	
Characteristic Variable	Statistic / Category	All Patients (N=1,206)	CUP Patients (N=119)	p-value
Age (yrs.)	Mean	65.9	65.7	0.8427
Clinical Stage	T1	892 (73.9%)	92 (77.3%)	
	T2	301 (25.0%)	25 (21.0%)	0.5279
	T3	13 (1.1%)	2 (1.7%)	
% Positive Cores	Mean (± SD)	33.2 ± 21.94	38.4 ± 22.88	0.0064
Pre-Biopsy PSA	0 - 4.0	177 (14.7%)	16 (13.4%)	
(ng/ml)	4.1 - 10	820 (68.0%)	82 (68.9%)	0.7530
	>10	209 (17.3%)	21 (17.7%)	
Gleason Score	6	577 (47.8%)	53 (44.5%)	
	7 (3 + 4)	337 (27.9%)	29 (24.4%)	
	7 (4 +3)	143 (11.9%)	26 (21.9%)	0.2733
	8	100 (8.3%)	5 (4.2%)	
	> 9	49 (4.1%)	6 (5.0%)	
AUA Risk	Low	486 (40.3%)	46 (38.7%)	
	Intermediate	506 (42.0%)	59 (49.6%)	0.4937
	High	214 (17.7%)	14 (11.8%)	
CCP Score	Mean ± SD	-0.7 ± 0.80	-0.7 ± 0.77	0.5183
	Range	(-2.8 to 2.0)	(-2.4 to 2.0)	0.5165
CAPM Risk	Mean ± SD	4.2 ± 5.07	4.1 ± 4.60	0.8587
10-year mortality (%)	Range	0.1 to 49	0.1 to 33	0.0307
Charlson	0	863 (71.6%)	88 (74.0%)	
Comorbidity Index	1	212 (17.6%)	21 (17.7%)	
	2	68 (5.6%)	2 (1.7%)	0.5002
	3	42 (3.5%)	6 (5.0%)	0.5003
	4	9 (0.7%)	1 (0.8%)	
	_	40 (4 00()	4 (0 00()	

Table 2	Changes	in	Number	of -	Trootmonto	Nagianad
Table 2.	Changes		number	OI	Treatments /	Assigned

All Patients (N=1,206)						
# of Treatment Options per Patient	Part A	Part B	Part C	Part D		
One	824 (68.3%)	854 (70.8%)	1,015 (84.2%)	1,051 (87.2%		
Two	169 (14.0%)	167 (13.9%)	139 (11.5%)	125 (10.4%		
Three	92 (7.6%)	80 (6.6%)	26 (2.2%)	18 (1.5%)		
Four or More	121 (10.0%)	105 (8.7%)	26 (2.2%)	12 (1.0%)		
Weighted Mean	1.72	1.64	1.24	1.16		
CUP Patients (N=119)						
One	58 (48.7%)	55 (46.2%)	106 (89.1%)	103 (86.6%		
Two	16 (13.5%)	18 (15.1%)	7 (5.9%)	12 (10.1%)		
Three	15 (12.6%)	15 (12.6%)	2 (1.7%)	1 (0.8%)		
Four or More	30 (25.2%)	31 (26.1%)	4 (3.4%)	3 (2.5%)		
Weighted Mean	2.66	2.67	1.19	1.19		

Table 3. Overall Changes in Treatment Modality

Part A Treatment Modality	Part D Physician Reported (and Audited) Outcomes			
	Non-Interventional	Interventional	Totals	
Non-Interventional	316	101	417	
Interventional	112	677	789	
Totals	428	778	1,206	
CUP Patients (N=119)				
Part A Treatment	Part D Physician Reported (and Audited) Outcomes			
Modality	Non-Interventional	Interventional	Totals	
Non-Interventional	23	9	32	
	4 4	72	87	
Interventional	14	73	01	

CONCLUSIONS

1 (0.8%)

The CCP test significantly influenced joint decision making towards appropriate personalized treatment in both the overall cohort and CUP subset.

12 (1.0%)

- 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.

REFERENCES

- 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.

Presented at AUA Southeastern Sectional Meeting - March 17, 2016