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

Philip Weintraub, MD, MBA;[1] Neal Shore, MD;[2] Adam Blatt, MD;[1] Shahin Chandrasoma, MD;[1] Lawrence Flechner, MD, PhD;[1] Gregory Barme, MD;[1] Judd Boczko, MD;[3] Naveen Kella, MD;[4] Brian J. Moran, MD;[5] Fernando J. Bianco, MD;[6] E. David Crawford, MD;[7] Rajesh Kaldate, MS;[8] Michael K. Brawer, MD;[8] Mark L. Gonzalgo, MD, PhD[9]

1) Skyline Urology, Burbank, CA 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

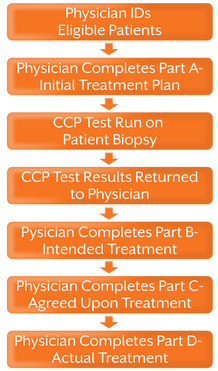
BACKGROUND

- 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 99 patients from Skyline Urology are presented.

METHODS

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 treatment recommendation (Part B), physician/patient consensus treatment decision (Part C), and physician reported (and audited) oucomes (Part D).
- 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 99 Skyline Urology patients with the remaining 1107 patients, across different clinical characteristics and utility measures.



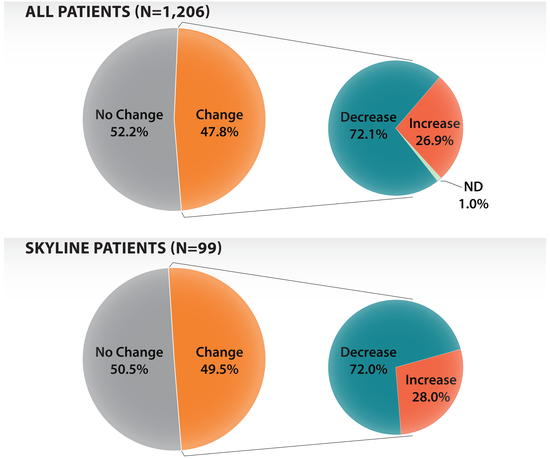
DESCRIPTION OF COHORT

- For the overall cohort, questionnaires were completed for 1206 individuals by 124 physicians from 24 states.
- For the Skyline subset analysis, questionnaires were completed for 99 individuals treated at Skyline Urology.
- Skyline is a large community practice consisting of 45 physicians at 33 offices throughout Southern California.

RESULTS

- Patient demographic and baseline characteristics are shown in Table 1, for both the full cohort and the Skyline subset.
- Table 2 shows that there was a significant reduction in the treatment burden for patients in the Skyline subset for each successive evaluation (P =0.0010).
  - The mean number of treatments per patient decreased from 1.87 pre-CCP test to 1.27 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 51% of the patients in the Skyline subset
  - 72% were reductions in treatment (Figure 1).
- Table 3 compares the changes in treatment modality for the Skyline subset with the cohort as a whole.
- A considerably high percentage of patients in the Skyline subset (40.4%; 40/99) were recommended for conservative management pre-CCP testing.
- These results support and mirror the data obtained from the entire patient cohort. No statistically significant difference was observed between the Skyline subset and the rest of the cohort.

Figure1. Changes in Treatment Following CCP Testing



Changes are shown from Part A (pre-CCP test) to Part D (physician reported outcomes)

Table 1. Patient Demographics and Baseline Characteristics

Characteristic Variable	Statistic / Category	All Patients (N=1,206)	Skyline Patients (N=99)	p-value
Age (yrs.)	Mean	65.9	66.6	0.3848
Clinical Stage	T1	892 (73.9%)	79 (79.8%)	0.1555
	T2	134 (25.0%)	20 (20.2%)	
	T3	13 (1.1%)	0	
% Positive Cores	Mean (± SD)	33.2 ± 21.94	32.8 ± 20.35	0.8196
Pre-Biopsy PSA Categorized	0 - 4.0	177 (14.7%)	13 (13.1%)	0.0543
	4.1 - 10	820 (68.0%)	60 (60.6%)	
	>10	209 (17.3%)	26 (26.3%)	
Gleason Score	6	577 (47.8%)	51 (51.5%)	0.3712
	7 (3 + 4)	337 (27.9%)	28 (28.3%)	
	7 (4 +3)	143 (11.9%)	8 (8.1%)	
	8	100 (8.3%)	8 (8.1%)	
	≥ 9	49 (4.1%)	4 (4.0%)	
AUA Risk	Low	486 (40.3%)	41 (41.4%)	0.5009
	Intermediate	506 (42.0%)	44 (44.5%)	
	High	214 (17.7%)	14 (14.1%)	
CCP Score	Mean ± SD Range	-0.7 ± 0.80 (-2.8 to 2.0)	-0.5 ± 0.88 (-2.2 to 1.9)	0.1477
CAPM Risk 10-year	Mean ± SD Range	4.2 ± 5.07 (0.1 to 49)	4.7 ± 5.95 (0.1 to 43)	0.3717
Charlson Comorbidity Index	0	863 (71.6%)	80 (80.8%)	0.0466
	1	212 (17.6%)	10 (10.1%)	
	2	68 (5.6%)	5 (5.1%)	
	3	42 (3.5%)	2 (2.0%)	
	4	9 (0.7%)	2 (2.0%)	
	≥5	12 (1.0%)	0 (0%)	

Table 2. Changes in Number of Treatments Assigned

All Patients				
Number of Treatment Options per Patient	Part A (N=1,206)	Part B (N=1,206)	Part C (N=1,206)	Part D (N=1,206)
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
Skyline Patients				
Number of Treatment Options per Patient	Part A (N=99)	Part B (N=99)	Part C (N=99)	Part D (N=99)
One	65 (65.7%)	69 (69.7%)	83 (83.9%)	83 (83.8)
Two	16 (16.1%)	14 (14.1%)	12 (12.1%)	10 (10.1%)
Three	9 (9.1%)	7 (7.1%)	1 (1.0%)	1 (1.0%)
Four or More	9 (9.1%)	9 (9.1%)	3 (3.0%)	5 (5.1%)
Weighted Mean	1.87	1.86	1.23	1.27

Table 3. Overall Changes in Treatment Modality

All Patients			
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
Skyline Patients			
Part A Treatment Modality	Part D Physician Reported (and Audited) Outcomes		
	Non-Interventional	Interventional	Totals
Non-Interventional	32	8	40
Interventional	6	53	59
Totals	38	61	99

CONCLUSIONS

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

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