

UNDERSTANDING PROSTATE CANCER

A GENE EXPRESSION TEST TO STRATIFY PATIENTS ACCORDING TO DISEASE AGGRESSIVENESS



Clinical Features

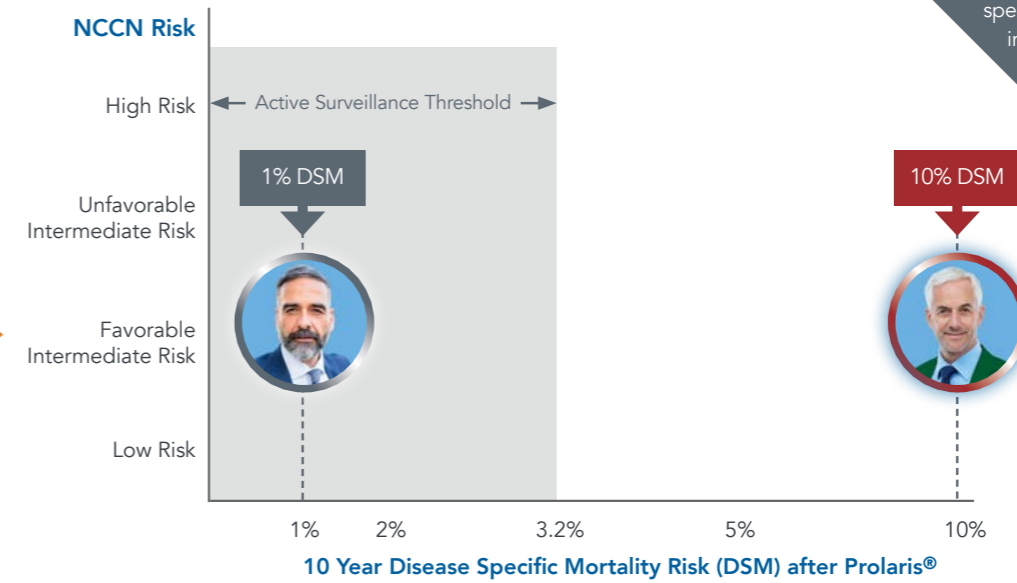
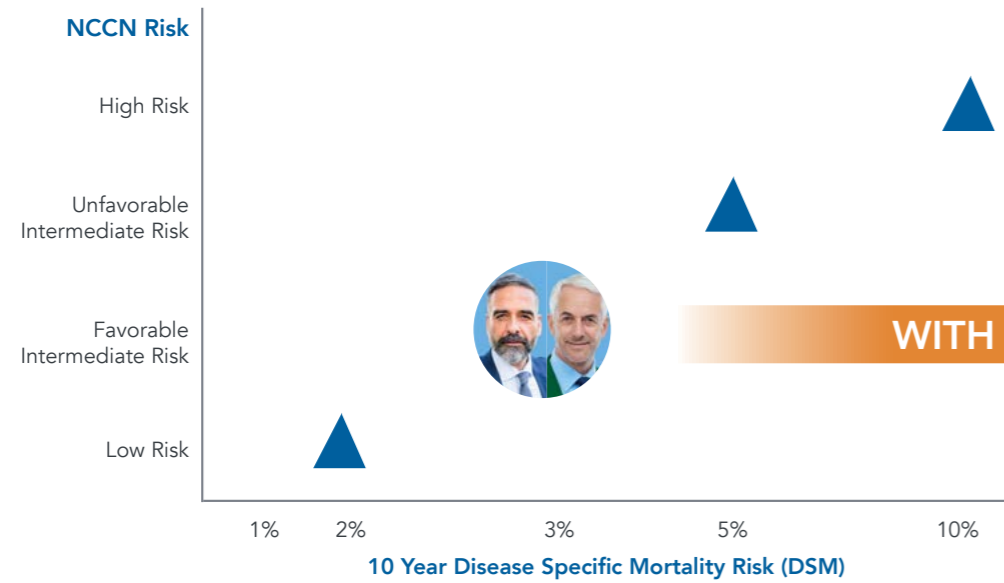
62 years old
PSA prior to biopsy: 8.0 ng/mL
Gleason: 3+4 = 7
Stage: T1c
% Positive Cores: <34%
National Comprehensive Cancer Network[®] (NCCN[®]): favorable intermediate risk

Proposed Treatment: Radical Prostatectomy

Same clinical features = **same treatment?**

CLINICOPATHOLOGIC FEATURES ARE NOT ENOUGH TO STRATIFY PROSTATE CANCER RISK.

PATIENTS WITH SIMILAR CLINICAL FEATURES... ..CAN HAVE VERY DIFFERENT OUTCOMES



Prolaris is included as an option for certain patients in NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®)*

"Retrospective studies have shown that molecular assays performed on prostate biopsy or radical prostatectomy specimens provide prognostic information independent of NCCN or CAPRA risk groups."

PROSTATE CANCER GUIDELINES

comprise all treatment modalities for low and intermediate risk patients, including **ACTIVE SURVEILLANCE.**¹

The Randomized European Study on Screening for Prostate Carcinoma (ERSPC) has shown that 40% of men undergoing screening are at risk of being treated for a biologically indolent disease that would not have altered their life expectancy.²

PROLARIS® PROVIDES

CRITICAL INFORMATION TO PERSONALIZE TREATMENT DECISIONS.

Molecular information and clinicopathologic features are combined to provide individual patient's 10-YEAR DISEASE SPECIFIC MORTALITY and 10-YEAR METASTASIS RISK.

Patient's 10-year prostate cancer specific mortality is reported and shown graphically, compared to a CUT-POINT which can be used to GUIDE PATIENT SELECTION FOR ACTIVE SURVEILLANCE OR DEFINITIVE TREATMENT.⁴

MOLECULAR ASSESSMENT OF CANCER AGGRESSIVENESS

provides unique information that differs from traditional clinicopathologic features. Prolaris® is a GENE EXPRESSION SIGNATURE based on cell cycle progression genes (CCP) that is a measure of how fast the cells in the prostate tumor are proliferating. Prolaris **DISTINGUISHES BETWEEN AGGRESSIVE AND INDOLENT TUMORS** more accurately than current clinical and pathologic features, enabling physicians to confidently tailor optimal treatment strategies for each patient.

PROLARIS® MOLECULAR SCORE IS 2 TIMES MORE PROGNOSTIC than Gleason and PSA.³

1. EAU PROSTATE CANCER - UPDATE 2020
2. Schroder FH, et al. Lancet 2014
3. Cuzick J, et al. BJC 2012

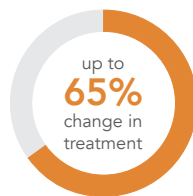
4. Lin DW, et al. Urologic Oncology: Seminars and Original Investigations 2018

ANALYTICAL VALIDITY: Robust and reproducible with a standard deviation of 0.1 units, representing only 1.6% of the range of scores seen in clinical validation studies.⁵

CLINICAL VALIDITY: 12 published studies on more than 4.000 patients from multiple cohorts.

PUBLICATION	SAMPLE TYPE	TREATMENT PARADIGM	ONCOLOGIC ENDPOINTS	N° OF PATIENTS
Cuzick J, et al. Lancet Oncol 2011 ⁶	RP	Radical Prostatectomy	Biochemical Recurrence	353
	TURP	Conservatively Managed	Disease-Specific Mortality	337
Cuzick J, et al. BJC 2012 ²	Biopsy	Conservatively Managed	Disease-Specific Mortality	349
Cooperberg MR, et al. J Clin Oncol 2013 ⁷	RP	Radical Prostatectomy	Biochemical Recurrence	413
Freedland SJ, et al. Int J Radiat Oncol Biol Phys 2013 ⁸	Biopsy	Primary External Beam Radiation	Biochemical Recurrence	141
Bishoff JT, et al. J Urol 2014 ⁹	Biopsy	Radical Prostatectomy	Biochemical Recurrence and Metastatic Disease	582
Cuzick J, et al. Br J Cancer 2015 ¹⁰	Biopsy	Conservatively Managed	Disease-Specific Mortality	585
Koch MO, et al. Cancer Biomarkers 2016 ¹¹	RP	Radical Prostatectomy	Metastatic Disease and Response to Salvage Radiation after BCR	47
Tosoian J, et al. BJU International 2017 ¹²	Biopsy	Radical Prostatectomy	Biochemical Recurrence	236
Lin DW, et al. Urologic Oncology: Seminars and Original Investigations. 2018 ⁴	Biopsy	Conservatively Managed	Disease-Specific Mortality	505
Canter DJ, et al. European Urology 2018 ¹³	Biopsy	Deferred treatment, Active Treatment	Metastatic Disease	767
Canter DJ, et al. Prostate Cancer and Prostatic Diseases 2019 ¹⁴	Biopsy	Radical Prostatectomy, radiotherapy	Metastatic Disease	1062
Kaul S, et al. Personalized Medicine 2019 ²⁰	Biopsy	Conservatively Managed	Any Disease Progression	664

CLINICAL UTILITY: Significant reductions in interventional treatment (radical prostatectomy and radiotherapy).¹⁵



In two clinical utility studies Polaris results lead to change in management in up to **65%** of patients^{15, 16}



Polaris expands active surveillance candidate population by **62%** compared to clinical and pathologic features alone⁴

WHY PROLARIS?

- Only test with an Active Surveillance Threshold and Disease Specific Mortality (DSM) endpoint validated in conservatively managed patients^{3,4,10}
- Stratifies risk of metastasis within 10 years¹⁴
- Only test validated in all Gleason scores^{3,4,6-12}



Rapid reporting of test results with an average 14-day from sample reception.

* Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer v2.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed September 3, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

5. Warf MB, et al. J Mol Biomark Diagn 2015
 15. Shore N, et al. J Urol 2016
 16. Crawford ED, et al. Curr Med Res Opin 2014



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