Prostate cancer continues to be a leading cause of cancer mortality in men. Approximately 1 man in 7 will be diagnosed with prostate cancer during his lifetime.¹

Early detection of prostate cancer is an important health care issue. The PSA test is the standard prostate cancer screening test administered by primary care physicians and urologists around the world. However, approximately 75% of prostate biopsies performed are negative for cancer, which calls out the need for a more specific test to help reduce unnecessary biopsies. The Prostate Health Index (phi) provides more accurate information that physicians require for better decision-making. If a patient has an elevated PSA test result in the 4-10 ng/mL range, this simple blood test is an option to determine their risk of prostate cancer and whether or not a biopsy is warranted.

The phi test utilizes a calculation that combines the results of three quantitative blood serum immunoassays (PSA, free PSA and p2PSA) into a single numerical result (the “phi score”). This score gives you more accurate information about what an elevated PSA level might mean and the probability of finding prostate cancer with a biopsy. The new and novel p2PSA assay is specific to measuring [-2]proPSA. The [-2] proPSA biomarker is an isoform of free PSA that was identified as the most prostate cancer-specific form found in tumor extracts.²
The Prostate Health Index: Filling the Diagnostic Gap

Results of the multi-center pivotal clinical trial showed that Beckman Coulter $\phi$ values significantly enhanced the clinical specificity for prostate cancer detection in men with PSA in the 4 to 10 ng/mL PSA range.$^4$ A Beckman Coulter $\phi$ value of 27.0 corresponds to 90% clinical sensitivity and 31.1% clinical specificity. Therefore, nearly $1$ in $3$ men may avoid prostate biopsy while detecting 90% of cancers if their Beckman Coulter $\phi$ value is less than 27.0.$^4$

Over 80 published clinical papers and meeting abstracts have demonstrated the benefits and economic value of the Prostate Health Index. These studies confirm that $\phi$ significantly improves clinical specificity for prostate cancer detection relative to PSA alone.

$\phi$ fills the diagnostic gap between PSA screening and a prostate biopsy. Combined with family and patient history, the $\phi$ score can be used to determine the best individualized patient management decisions.
The Prostate Health Index: Its Utility in Prostate Cancer Detection

Publication/Authors:
Lepor A, Catalona WJ, Loeb S

Study Overview/Objective:
This article reviews the major studies on phi in prostate cancer detection and risk stratification.

Key Points:
› The Prostate Health Index (phi) addresses many of the drawbacks associated with PSA screening
› The specificity of phi is greater because phi is a combination of three different isoforms of PSA: total PSA, free PSA, and [-2]proPSA
› The Prostate Health Index is a simple blood test, but it outperforms any of its individual components for the identification of clinically significant prostate cancer
› The phi test is more specific for the detection of clinically significant prostate cancer than free and/or total PSA
› Increasing phi scores predict a greater risk of high-risk pathology and biochemical recurrence after radical prostatectomy
› The phi test performed at the initiation and during the course of active surveillance predicts subsequent biopsy reclassification

Article Conclusion:
Numerous large, prospective studies from geographically diverse regions have consistently demonstrated that phi is more specific for prostate cancer detection than existing standard reference tests of total and free PSA. Increasing phi scores predict a greater risk of clinically significant disease on biopsy and adverse prostatectomy outcomes.
Serum Marker %[-2]proPSA and the Prostate Health Index Improve Diagnostic Accuracy for Clinically Relevant Prostate Cancer

Publication/Authors:
Robert W. Veltri

Publication Overview:
This article was an Editor’s Choice letter published in the British Journal of Urology International by Dr. Robert W. Veltri, at the Department of Urology, Brady Urological Institute, Johns Hopkins University School of Medicine, Baltimore, MD, USA.

Key Point:
› A multi-center study by Boegemann et al. assessed 769 men aged ≤ 65 years at their initial and repeat prostate biopsy diagnoses and %[-2]proPSA and phi were shown to be the strongest predictors of biopsy outcome

Article Conclusion:
Currently, evaluation of high-risk cancer is often based on genomic knowledge and has -70–75% accuracy to offer personalized treatment regimens. The study by Boegemann et al. achieved similar accuracy using phi and routine clinicopathological features to create models for prostate cancer detection and repeat biopsy decision-making. Clearly, a prostate cancer risk predictor containing the best biomarkers, including phi, will improve the accuracy in the management of patients on active surveillance.
The Prostate Health Index (phi) Selectively Identifies Clinically-Significant Prostate Cancer

Publication/Authors:

Study Objective:
The authors investigated whether phi improves specificity for detecting clinically significant prostate cancer and can help reduce prostate cancer overdiagnosis.

Study Overview:
› From the multi-center prospective trial, 658 men aged 50 years or older were identified with PSA 4 to 10 ng/mL and normal digital rectal examination who underwent prostate biopsy
› In this population, the performance of PSA, % free PSA, p2PSA and phi were compared to predict biopsy results and, specifically, the presence of clinically-significant prostate cancer using multiple criteria

Key Points:
› Results showed that phi was significantly higher in men with Gleason 7 or greater and “Epstein significant” cancer
› On ROC analysis, phi had the highest AUC for overall cancer, Gleason 7 or greater and significant cancer (see table below)
› At the 90% sensitivity cut off point for phi (a score less than 28.6) 30.1% of patients could have been spared an unnecessary biopsy for benign disease or insignificant cancer compared to 21.7% using % free PSA

<table>
<thead>
<tr>
<th>Test/Biomarker</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
</tr>
<tr>
<td>phi</td>
<td>0.708</td>
</tr>
<tr>
<td>% free PSA</td>
<td>0.648</td>
</tr>
<tr>
<td>p2PSA</td>
<td>0.550</td>
</tr>
<tr>
<td>PSA</td>
<td>0.516</td>
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</tbody>
</table>

Article Conclusion:
The phi test outperforms its individual components of total, free and p2PSA for the identification of clinically-significant prostate cancer. The Prostate Health Index may be useful as part of a multivariable approach to reduce prostate biopsies and over diagnosis.
Clinical Performance of Serum [-2]proPSA Derivatives, %p2PSA and phi in the Detection and Management of Prostate Cancer

Publication/Authors:
Huang Y, Sun T, Zhong W, Wu C

Study Overview/Objective:
A systematic review of the available scientific evidences was performed to evaluate the potentials of %p2PSA and phi in clinical application. The review was focused on their application in diagnosis and active surveillance.

Key Points Regarding p2PSA:
› In histological analyses, proPSA was differentially expressed in the peripheral zone while undetectable in the transition zone in most prostate specimens leading to the conclusion that proPSA appears to be a more cancer-specific form of PSA
› Amino acid sequencing of whole purified PSA, isolated and tissues, showed that the proPSA in peripheral zone cancer consisted mainly of [-2]proPSA (p2PSA) rather than other proPSA

Key Points Regarding phi:
› Increased phi levels were strongly associated with patients harboring more aggressive diseases
› Furthermore, phi demonstrated potential ability to identify the progress of low-risk localized cancer under active surveillance
› The phi test also showed potential association with probability of metastatic progression and biochemical recurrence after radical prostatectomy
› Studies showed that if phi was added to the current prostate cancer screening strategies, overall reductions in cost can be achieved due to the reduction in the total number of office visits, laboratory tests and unnecessary biopsies

Article Conclusion:
Studies suggest that phi enhances the accuracy of detection, reduces the number of unnecessary biopsies and helps predict the aggressiveness of prostate cancer when compared to total PSA and free PSA.
2015

2014
Loeb S, Catalona W. The Prostate Health Index: a new test for the detection of prostate cancer. Therapeutic Advances in Urology 2014; 6(2) 74-77.
Ng C, Peter C, Lam N, Lam H, Kim L, Simon H. The prostate health index in predicting initial prostate biopsy outcomes in Asian men with prostate-specific antigen levels of 4-10 ng/mL. Int Urol Nephrol 2014 Apr; 46(4):711-7.

2013


2012


2011


2010


References:


4. p2PSA IFU

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