

Complexed PSA— Peer-Reviewed Clinical Studies

The detection and potential economic value of complexed prostate specific antigen as a first line test.

Babaian RJ, et al. J Urol. 2006;175:897-901.

Design: A multisite study of men who underwent transrectal ultrasound-guided biopsies. A subset (467/1,362) of patients with total PSA between 2.5 and 6 ng/mL were evaluated to compare cancer detection rates, specificity, and the number biopsies for total PSA and complexed PSA. Total PSA and complexed PSA were determined, respectively, using the ADVIA Centaur® PSA and cPSA assays.

Results: Overall cancer detection rates were similar for total PSA (31.5%) and complexed PSA (32.6%) within equivalent assay ranges (total PSA, 2.5 to 6 ng/mL; complexed PSA, 2.2 to 5.1 ng/mL). The diagnostic accuracy determined by ROC analysis for differentiating between prostate cancer and benign disease was higher for complexed PSA: total PSA AUC of 0.639 versus a complexed PSA AUC of 0.682. At each level of sensitivity evaluated, complexed PSA had a higher specificity than total PSA. This led the authors to estimate that complexed PSA at sensitivities of 95%, 90%, and 85% could have avoided 13.7%, 21.6% and 28.7% of biopsies, and the use of total PSA at sensitivities of 95%, 90%, and 85%, could have avoided 9%, 16.7%, and 23.6% of biopsies. At 95% sensitivity, the 4.7% difference in the biopsies saved by using complexed PSA was significant ($P = 0.0003$).

Conclusions: Complexed PSA is at least as good as total PSA for the detection of prostate cancer and has the added benefit of increased specificity, which may result in fewer biopsies.

Complexed PSA improves prostate cancer detection: results from a multicenter Japanese clinical trial.

Okihara K, et al. Urology. 2006;67(2):328-32.

Design: A total of 760 men whose total PSA values ranged from 1.0 to 100 ng/mL were included. Serum samples for total PSA and complexed PSA were obtained in all cases. The study evaluated results at various cutoff values for complexed PSA compared to a total PSA cutoff of 4.0 ng/mL.

Results: Prostate cancer was detected in 268 (35.3%) of 760 patients. ROC analysis showed better performance ($P < 0.001$) for complexed PSA vs. total PSA with AUC values of 0.741 and 0.721, respectively. At sensitivities of 80%, 85%, 90% and 95%, complexed PSA was significantly more specific than total PSA: 49.6% vs. 43.5%, $P = 0.0239$; 41.3% vs. 36.8%, $P = 0.0042$; 33.7% vs. 27.6%, $P = 0.00439$; and 22.8% vs. 18.5%, $P = 0.0068$.

Conclusions: This study showed that complexed PSA performs better than total PSA as an aid in the diagnosis of prostate cancer and has higher specificity.

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Complexed prostate-specific antigen for the diagnosis of biochemical recurrence after radical prostatectomy.

Parsons JK, et al. BJU Int. 2007;99:758-61.

Design: This study evaluated the validity of using complexed PSA for diagnosing biochemical recurrence after radical prostatectomy. The primary study outcomes were correlation between total PSA and complexed PSA; determination of complexed PSA values equivalent to total PSA values of 0.2 and 0.4 ng/mL; and the sensitivity, specificity, predictive values, and likelihood ratios of complexed PSA for detecting biochemical recurrence. A secondary outcome was the correlation of complexed PSA to total PSA in monitoring patients diagnosed with biochemical recurrence. This study included 150 men who had a retroperitoneal radical prostatectomy for clinically localized prostate cancer at a single tertiary care center and who had detectable serum levels of total PSA ranging from 0.03 to 1.08 ng/mL after surgery. In addition, 144 specimens from 15 men previously diagnosed with biochemical recurrence based on total PSA levels of ≥ 0.2 ng/mL were analyzed. Total PSA and complexed PSA were determined, respectively, using the ADVIA Centaur PSA and cPSA assays.

Results: Using a regression model, total PSA and complexed PSA levels correlated closely among patients with PSA values of < 1.0 ng/mL ($r = 0.99$) after radical prostatectomy and among patients who were diagnosed with biochemical recurrence ($r = 0.99$). Total PSA values of 0.2 and 0.4 ng/mL corresponded to complexed PSA values of 0.12 ng/mL (95% CI, 0.08–0.17 ng/mL) and 0.29 ng/mL (95% CI, 0.22–0.28 ng/mL). Using a complexed PSA cutoff of 0.12 ng/mL for recurrence, sensitivity was 96%, specificity was 88%, positive predictive value was 89%, negative predictive value was 88%, positive likelihood ratio was 8, and negative likelihood ratio was 0.05. Using a complexed PSA cutoff of 0.29 ng/mL for recurrence, sensitivity was 96%, specificity was 96%, positive predictive value was 96%, negative predictive value was 96%, positive likelihood ratio was 24, and negative likelihood ratio was 0.04.

Conclusions: Complexed PSA is as good as total PSA for determination of biochemical recurrence in patients after radical prostatectomy. Complexed PSA is a useful aid for monitoring patients after radical prostatectomy.

Complexed PSA (cPSA) is FDA cleared as an aid in the diagnosis of prostate cancer used in conjunction with digital rectal examination for men age 50 years and older. It is also approved as an aid in the management/monitoring of patients with prostate cancer.

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