Capillary Self-Sampling in Organized Prostate Cancer Testing Using Capitainer®B – Clinical Validation and a Randomized Implementation Study

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Conclusions

1. Clinical validation

The performance study showed that PSA analysis using self-collected dried blood samples demonstrated good analytical performance and good correlation with the routine plasma PSA method.

2. Randomized study

The randomized clinical study within Organized Prostate Cancer Testing (OPT) showed significantly higher participation among men offered self-sampling compared with those offered venous blood sampling at a primary care center ($p = 0.009$).

Next Steps

A larger implementation study (n = 7,000 men) is being planned within OPT in RCC Norr, and automation of the analytical method is under development in Region Stockholm.

Figure 1. Capitainer®B self-sampling device.
During sampling, 10 µL of blood is automatically metered from a drop of blood and transferred to a pre-punched paper disc. Each sampling card accommodates two individual samples. The blood then dries during transport by regular mail to the analytical laboratory.

Introduction

Most regions in Sweden offer men aged 50–74 years testing for prostate-specific antigen (PSA) as part of Organized Prostate Cancer Testing (OPT). Currently, the participation rate for first-time testing is approximately 35%.

Study Objectives

1. To validate a self-sampling method for PSA testing.
2. To investigate whether participation in OPT increases when at-home self-sampling is offered.

Methods

Clinical validation

In an IVDR-compliant performance study, parallel venous blood sampling and self-sampling using Capitainer®B (Figure 1) were performed for PSA analysis in 100 men. PSA was analyzed using the Siemens Atellica IM for all samples. For the method comparison, the correlation coefficient (R) was calculated, and an equation describing the relationship between plasma PSA and Capitainer PSA was derived. This equation was used to convert Capitainer PSA results to corresponding plasma PSA values. Based on these converted results, the diagnostic sensitivity and specificity of self-sampling were calculated at the OPT decision thresholds (1.0 and 3.0 µg/L). Imprecision (CV) for the self-sampling method was also calculated.

Randomized study

A total of 997 men (aged 50 or 56 years) from Region Västerbotten were randomized into two groups (1:1) and invited by mail to participate in the study. The reference group was instructed to book an appointment for venous blood sampling, while the intervention group received a self-sampling kit. The primary outcome of the study was the participation rate within three months.

Results

Clinical validation

Plasma PSA concentrations among the participating men ranged from 0.1 to 32.5 µg/L (median 4.3 µg/L). The correlation between the methods was very good (R = 0.985, Figure 2). For Capitainer PSA, the CV was 8%, based on the variation between duplicate capillary samples collected from the same individual (n = 86).

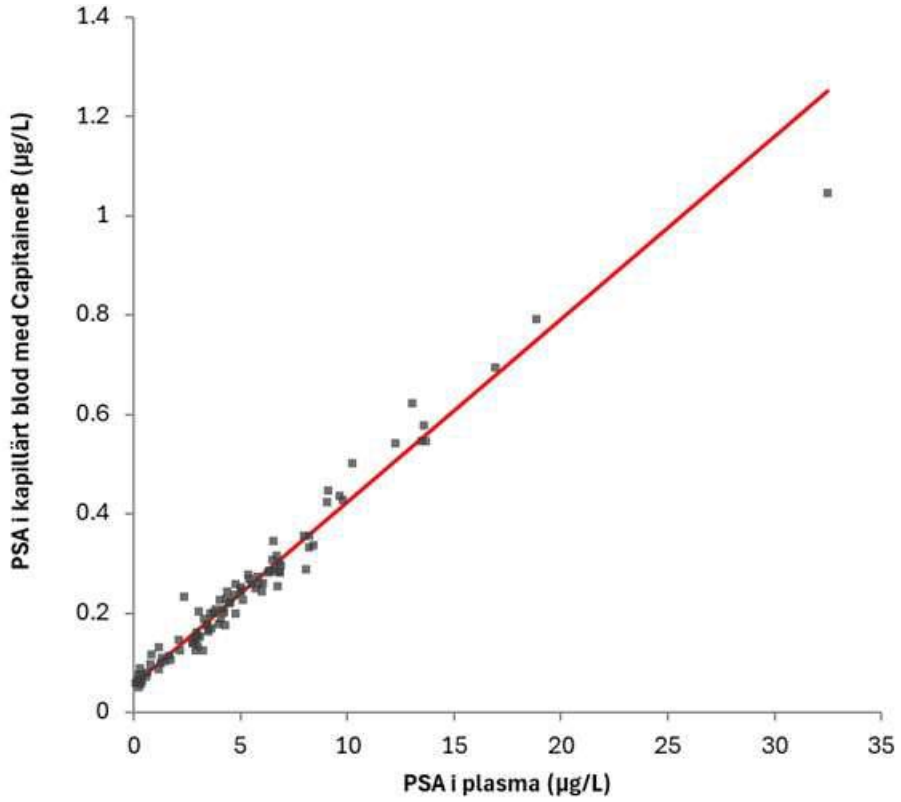

Figure 2.

Correlation between Capitainer PSA in dried blood following capillary self-sampling and plasma PSA (reference method) (R = 0.985).

For converted Capitainer PSA values, diagnostic sensitivity and specificity were 94% and 100%, respectively, at the PSA decision threshold of 3.0 µg/L, and 98% and 100%, respectively, at the PSA decision threshold of 1.0 µg/L. Plasma PSA was used as the reference method.

Randomized study

In the self-sampling group, 185 participants (37.8%) submitted a sample, of which 180 (97.3%) were successful. In the reference group, 143 participants (29.8%) submitted a sample, of which 142 (99.3%) were successful. The difference in participation rate between the groups was statistically significant ($p = 0.009$). The CV for Capitainer PSA in this study was 16%, based on the variation between duplicate capillary samples collected from the same individual ($n = 152$).