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ORIGINAL ARTICLE

Percent free prostate-specific antigen for prostate cancer diagnosis in Chinese men with a PSA of 4.0–10.0 ng/mL: Results from the Chinese Prostate Cancer Consortium

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ROC curve

Abstract *Objective:* To test the diagnostic performance of percent free prostate-specific antigen (%fPSA) in predicting any prostate cancer (PCa) and high-grade prostate cancer (HGPCa) in a retrospective multi-center biopsy cohort with a PSA level of 4.0—10.0 ng/mL in China.
Methods: Consecutive patients with a PSA of 4.0—10.0 ng/mL who underwent transrectal ultrasound-guided biopsy were enrolled at 16 Chinese medical centers from January 1st, 2010 to December 31st, 2013. Total and free serum PSA determinations were performed using three types of electro-chemiluminescence immunoassays recalibrated to the World Health Organization (WHO) standard. The diagnostic accuracy of PSA, %fPSA, and %fPSA in combination with PSA (%fPSA + PSA) was determined using the area under the receiver operating characteristic (ROC) curve (AUC).
Results: A total of 2310 consecutive men with PSA levels between 4.0 and 10.0 ng/mL were included, and the detection rate of PCa was 25.1%. The AUC of %fPSA and %fPSA + PSA in predicting any PCa was superior to PSA alone in men aged ≥60 years (0.623 *vs.* 0.534, $p < 0.0001$) but not in men aged 40—59 years (0.517 *vs.* 0.518, $p = 0.939$). Similar result was yield in predicting HGPCa.
Conclusion: In a clinical setting of Chinese men with 4.0—10.0 ng/mL PSA undergoing initial prostate biopsy, adding %fPSA to PSA can moderately improve the diagnostic accuracy for any PCa and HGPCa compared with PSA alone in patients ≥60 but not in patients aged 40—59 years.

1. Introduction

Prostate cancer (PCa) is the second-most frequently diagnosed malignancy in men globally [1]. Although the incidence of PCa in China is much lower than in Western countries [2], PCa ranks as the fastest growing malignancy with respect to incidence in recent years [3,4] due to changing lifestyles and increasing health awareness. Although new biomarkers are emerging, prostate-specific antigen (PSA) and its derivatives remain the most widely used and practical test to detect PCa. Percent free PSA (%fPSA) has been demonstrated to improve positive test results during prostate biopsy and to reduce the number of unnecessary biopsies in men with a moderately elevated serum PSA level (4.0—10.0 ng/mL) in white and black populations [5,6]. The diagnostic accuracy (area under the receiver operating characteristic curve, AUC) has been reported to be approximately 0.7 in patients with a PSA of 4.0—10.0 ng/mL [7,8]. However, PCa is believed to differ epidemiologically and biologically between Western and East Asian populations. First, the age-standardized PCa incidence rate in China was reported to be 5.3/100,000 in 2012 by the World Health Organization (WHO), which was only 1/12 of the rate in European populations and 1/18 of the rate in North Americans [9]. In addition, PSA reference ranges have been reported to be much lower in Chinese and Japanese populations [10,11]. Thus there may also be some other differences in the application of %fPSA in East Asian population.

Although several studies of %fPSA in China indicated an improvement in diagnostic accuracy over PSA alone [12,13], these studies were mostly published in Chinese journals with limitations with respect to sample size. In this study, we attempted to examine the effectiveness of %fPSA in a retrospective multi-center Chinese cohort.

2. Methods and materials

2.1. Patients

This study was approved by the Institutional Review Board of each of the participating hospitals. This study involved 2310 consecutive patients who underwent transrectal ultrasound (TRUS)-guided prostate biopsy in 16 participating hospitals between January 1st, 2010 and December 31st, 2013. Patients visiting the outpatient department of urology for health checkups and urinary symptoms with a PSA of 4.0—10.0 ng/mL were included in this study, regardless of digital rectal examination (DRE) results. Patients with prior biopsy, urinary tract infections, urinary retention or instrumentation or catheterization of the urethra within 2 weeks and those received finasteride or hormonal treatment were excluded. TRUS-guided systematic 8-, 10- and 12-core biopsies were performed in 490, 483 and 1337 patients, respectively.