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Original article

Association of serum prostate-specific antigen levels with the results of the prostate needle biopsy

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Association entre le taux d'antigène prostatique sérique et les résultats des biopsies prostatiques

Keywords
Prostate cancer
Prostate specific antigen
Prostate needle biopsy

Summary

Aim > To investigate the relationship of serum prostate-specific antigen (PSA) levels with outcomes of prostate needle biopsy in men 50 or more years old.
Methods > We measured serum PSA levels in 1472 healthy men 50 or more years old. Men who had serum PSA values 4.0 ng/mL or higher underwent digital rectal examination. If there were either an elevated PSA level ($\geq$ 4 ng/mL) or abnormal digital rectal examination, a transrectal ultrasound-guided prostate biopsy was performed.
Results > The mean serum total PSA level was 13.73 $\pm$ 11.44 ng/mL, and the mean serum free PSA level was 4.99 $\pm$ 0.97 ng/mL. Of the 260 men who had serum total PSA levels of $\geq$ 4 ng/mL, 139 underwent biopsy. Of these 139 men, 45 (32.4%) had prostate cancer. Benign prostatic hyperplasia with or without prostatitis was diagnosed in 94 patients (67.6%). There was no significant correlation between age and histologic results of prostate needle biopsy (*P*-value = 0.469). The serum free PSA showed no significant correlation with histologic results of prostate needle biopsy, whereas the serum total PSA level had a significant correlation in patients with adenocarcinoma compared with other diagnosis.
Conclusions > The overall frequency of detection of prostate adenocarcinoma was 32.4%. This study revealed that no level of PSA was associated with a 100% positive predictive value and negative biopsy can occur virtually at any PSA level. There is a need to create awareness among the general population and health professionals for an early diagnosis of this common form of cancer.

Mots clés
Cancer de la prostate
Antigène prostatique
Biopsie prostatique

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Introduction

Prostate cancer is one of the most common cancers affecting men with > 1,100,000 new cases and 300,000 deaths worldwide each year [1]. About 9.7% of cancers in men are due to prostate cancer; in developed parts of world it increases to 15.3% and in the underdeveloped world it only accounts for 4.3% [2]. Prostate cancer often grows, so slowly that most men die of other causes before the disease becomes clinically advanced. Thus, a screening program that could identify asymptomatic men with aggressive localized tumors might be expected to substantially reduce prostate cancer morbidity, including urinary obstruction and painful metastases, and mortality. Most men with early stage prostate cancer have no symptoms attributable to the cancer.

Prostate-specific antigen (PSA) testing revolutionized prostate cancer screening. Today, there are still no recommendations for mass screening from the health authorities. On the contrary, hesitation and downright negative attitudes are the rule due to the weaknesses of the PSA test, the side effects of treatment and the highly variable natural history of the cancer [3,4]. Screening for prostate cancer cannot be justified in low-risk populations, but the balance of benefit and harm will be more favourable after risk stratification. Prostate cancer screening can be justified only in research programmes designed to assess its effectiveness and help identify the groups who may benefit [5]. The majority of these newly-diagnosed cancers were clinically localized, which led to an increase in radical prostatectomy and radiation therapy, aggressive treatments intended to cure these early-stage cancers [6–8].

Men with abnormal prostate exams (nodules, induration, or asymmetry) should be referred to an urologist for a prostate biopsy, with a histologic diagnosis based upon tissue obtained from the biopsy. A prostate biopsy may also be indicated based upon abnormal PSA values. PSA-based screening commonly results in biopsy in patient with serum PSA levels of > 4.0 µg/L with a detection rate of 30–35% for prostate cancer [9].

The aim of the present study was to investigate the role of abnormal PSA levels in the detection of prostate cancer in men and relationship of serum PSA levels with histologic results of prostate needle biopsy.

Materials and methods

Study design

This was a prospective cross-sectional study carried out in the Department of Pathology, in collaboration with the Department of Urology at a medical college hospital, which is the largest public sector hospital in Ardabil City, Iran. The duration of the study was a period of 6 years from May 2008 to June 2013.

A total of 1472 healthy men 50 or more years old were enrolled in this study. All patients were assessed by a thorough history, physical examination and routine laboratory investigations. Men with a history of prostate cancer, or a history of previous prostate surgery (transurethral resection of the prostate or open prostatectomy), and those with a history of prostatitis were excluded from the study. Patients were also excluded from the study if they had received 5-alpha-reductase inhibitors, or had an indwelling catheter or evidence of urinary tract infection. We measured serum PSA levels in 1472 healthy men 50 or more years old. Men who had serum PSA values 4.0 ng/mL or higher underwent digital rectal examination. If there were either an elevated PSA level ($\geq$ 4 ng/mL) or abnormal digital rectal examination, a transrectal ultrasound (TRUS)-guided prostate biopsy was performed. Written informed consent was obtained from the participants.

Serum PSA measurement

Serum PSA concentrations were measured by radioimmunoassay with kits (Tandem R-Prostate specific antigen) obtained from Hybritech. The Tandem-R assay is one of the original manual assays used for measurement of PSA. The PSA samples were reacted with a plastic bead coated with a monoclonal antibody that had an affinity for a specific PSA epitope. According to the manufacturer's recommendations, the normal range for PSA using this assay was 0 to 3.9 ng/mL.

Digital rectal examination

The digital rectal examination is a relatively simple procedure. The patient undressed, then was placed in a position where the anus was accessible (lying on the side, squatting on the examination table, bent over the examination table, or lying down with feet in stirrups). Digital rectal examination findings were categorized as normal, abnormal but benign (including any enlargement or asymmetry), or arousing suspicion of cancer (including the presence of induration).

TRUS-guided prostate biopsy

Each patient underwent eight-core biopsy with an 18-gauge automatic Tru-Cut biopsy needle (TSK, Tokyo, Japan) under local anesthetic infiltration peri-prostatic nerves with 10 mL of 1% lidocaine (without adrenaline). All biopsies were carried out by either a trainee or an experienced urologist while performing trans-rectal ultrasound with the patient in a lateral decubitus position. Hematoxylin-eosin-stained slides taken from archival sections of biopsied prostatic tissue were analyzed by one pathologist.

Statistical analysis

The statistical analysis of the data was done using SPSS software (Version 19.SPSS Inc., United States). ANOVA analysis was performed using a two-sample *t*-test with equal variances for continuous variables and a Pearson χ^2 test to compare categorical variables. A *P*-value of < 0.05 was considered statistically significant. The results were expressed as means $\pm$ standard deviations.

Results

A total of 1472 healthy men 50 or more years old with a mean age of 57.70 $\pm$ 23.35 years (range: 50 to 89 years) were