### **Original Article**

# Study on individualized prostate biopsy guided by prostate specific antigen at different ranges

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#### **Abstract**

**Background:** Prostate specific antigen (PSA) is the most commonly used indicator for screening of prostate cancer(PCa), and the studies on PSA in PCa are very extensive at present. How to effectively use this indicator is worth for further study which this article wish to address.

**Objective:** The aim of this study is to explore how PSA in different ranges can better guide the individualized prostate biopsy.

**Methods:** A total of 117 patients with suspected PCa admitted to the Affiliated Hospital of Chengde Medical College from October 2018 to July 2020 were selected as the research subjects. PSA level and ratio of free and total PSA (F/TPSA) value of each patient were measured, and ultrasound-guided transrectal prostate biopsy was conducted for each patient, and then the PSA measurement results were compared with the prostate biopsy results.

**Results:** The result of biopsy was PCa in 40 cases, BPH in 77 cases. The positive expression rates of Group I in BPH and PCa patients were 25.97% and 87.50%, respectively, and the difference was statistically significant (P < 0.05). The positive expression rates of Group II in BPH and PCa patients were 10.39% and 75.00%, respectively, and the difference was statistically significant (P < 0.05). The sensitivity, specificity, positive predictive value and diagnostic coincidence rates of Group I and Group II were 87.50%, 74.03%, 63.63%, 78.63% and 75.00%, 89.61%, 78.94% and 84.62%, respectively.

**Conclusion:** Under different TPSA intervals, F/T < 0.16 has different diagnostic efficacy for PCa. Group I is more sensitive and suitable for early screening. Group II has stronger specificity in the diagnosis of PCa, Higher diagnostic coincidence rate, and has more diagnostic advantages before biopsy. Selecting Group II can help clinicians make more patient-friendly decisions and reduce the incidence of complications related to biopsy. According to patients' aspiration for biopsy, auxiliary examinations such as magnetic resonance scan of prostate and bone scan should be performed actively for patients who meet the criteria I if they refuse to undergo biopsy. On the premise of not affecting PCa secondary prevention as much as possible, a more individualized biopsy plan was developed for patients.

Keywords: PCa, PSA, Individualized biopsy

#### Introduction

The incidence of PCa in China is increasing year by year, which has a negative impact on the health and quality of life of middle-aged and elderly men. This rise in incidence has to do with an aging population, changes in diet and lifestyle habits, and advances in medical technology. At

present, trans-rectal or trans-perineal prostate biopsy is still the gold standard for the diagnosis of prostate cancer. PSA and its derivatives are still commonly used in screening of PCa, but regional differences will reduce the detection efficiency of the indicators. Some articles have mentioned that

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the gray area of 4-10ng /mL is not as applicable in China as it is in Western countries. The ideal screening Group should have high sensitivity and specificity, but PSA is not able to meet our needs at present.1-3 In this study, we retrospectively evaluated the clinical data of patients with suspected prostate cancer in our hospital from October 2018 to July 2020 to explore and analyze the clinical application value of PSA expression combined with prostate biopsy results in Chengde area. The purpose of this study was to study the individualized prostate biopsy program for patients with suspected PCa in the Chengde area. As far as possible, the secondary prevention of PCa is not affected on the basis of reducing the workload of prostate biopsy and reducing the incidence of complications. As far as possible, the secondary prevention of PCa is not affected on the basis of reducing the workload of biopsy and reducing the incidence of complications.

#### **Methods**

Study design and settings: A total of 117 patients with suspected PCa visiting the Affiliated Hospital of Chengde Medical College from October 2018 to July 2020 were selected as the research subjects, and grouped according to the biopsy results. The results showed that PCa was regarded as positive (+) and BPH as negative (-), with a positive rate of 33.90% (40/117). There were 77 BPH patients, ranging in age from 49 to 89 years old, with an average age of (69.53±8.01) years old. Forty PCa patients ranged in age from 58 to 98 years, with an average age of (71.15±8.08) years. There was no significant difference in age between the two groups (t=1.03,P > 0.05).This study has been approved by the Ethics Committee of the university.

**Inclusion criteria:** Patients with PCa and BPH confirmed by needle biopsy and without other malignant tumors are included in the study.

**Exclusion criteria:** (1) patients with acute urinary tract infection (2) patients undergoing digital rectal examination, indwelling catheter, or cystoscopy. (3) patients who are already on 5 alfa reductase inhibitor (Finasteride/ dutasteroid like drugs. (4) patients with other malignant tumors. (5) patients whose conditions were complex and difficult to evaluate the effectiveness. (6) patients

who could not complete the test or quit the test.

**Detection method:** PSA level of each patient was measured by chemiluminescence method, and F/TPSA value was calculated. Then, ultrasoundguided transrectal prostate biopsy was performed for each patient. Antibiotics were used for prophylaxis before biopsy, and routine cleaning enema was required before operation. During the biopsy, the patient lies in the left side decubitus position and holds the knees with both hands, so that the legs are close to the abdomen and the anus is fully exposed. After disinfection, the transrectal probe was inserted into the rectum. The coronal and sagittal sections of sonographic images of the prostate were carefully observed to find out whether there were suspicious lesions, and the size of the prostate was measured. The peripheral zone, apex, base and middle part of the prostate were selected for biopsy. After biopsy, the specimens were fixed and sent for examination.

**To observe:** Before biopsy, the patients were divided into Group I and Group II according to the PSA situation. Group I represented TPSA≥4ng/ml and F/TPSA < 0.16. The measured PSA value of patients was positive (+) in line with Group I, otherwise it was negative (-). Group II represents TPSA≥10ng/ml and F/TPSA < 0.16. PSA measured in accordance with Group II is defined as (+); otherwise, it is negative (-).

**Statistical analysis:** SPSS20.0 software was used for analysis.Measurement data were expressed as mean±standard deviation, and t test was used. Enumeration data were expressed as percentage (%), and Pearson chi-square test was used. P < 0.05 was considered statistically significant.

#### **Results**

## **Trucut biopsy results at different PSA ranges:**

Biopsy results showed 40 patients with PCa and 77 patients with BPH. The positive expression rates of Group I in BPH and PCa patients were 25.97% and 87.50%, respectively, and the difference was statistically significant (P<0.05). The positive expression rates of Group II in BPH and PCa patients were 10.39% and 75.00%, respectively, and the difference was statistically significant (P<0.05). The chi-square value of Group

I was significantly lower than that of Group II, indicating that Group II had a more significant correlation with the positive rate of prostate Biopsy. The sensitivity, specificity, positive predictive value, and diagnostic coincidence rates of Group I and Group II were 87.50%, 74.03%, 63.63%, 78.63%, and 75.00%, 89.61%, 78.94%, and 84.62%, respectively, as shown in table 1.

**Table 1:** Comparison of Group I and Group II combined with prostate needle biopsy

	Number of	Group I	Group II
	cases (n=117)	(+) (-)	(+) (-)
Trucut biopsy PCa (-)	77	20 57	8 69
results BPH (+)	40	35 5	30 10
χ 2		40.00	50.11
Р		<0.05	<0.05
Sensitivity/True		07.50	75.00
Positive (%)		87.50	75.00
Specificity/True		74.03	89.61
Negative (%)		74.03	09.01
Diagnostic coincidence		70.62	04.63
rate (%)		78.63	84.62
Positive predictive		C2 C2	70.04
value (%)		63.63	78.94

#### **Discussion**

The incidence of PCa in middle-aged and elderly male patients in China is increasing every year, which not only seriously affects the physical and mental health and the quality of life of patients, but also brings a heavy burden to the national medical system. PSA is a protease that liquefies the sperm plasma and increases sperm motility. There is a protective barrier between the blood lymphatic micro circulation network and the prostatic acinus in normal prostate, but when the capillary and lymphatic duct wall are damaged, PSA in the acinus will enter the blood (PCa invasion), thus causing the increase of PSA in the blood.4 However, PSA is affected by many factors and lacks specificity. Nevertheless, PSA is still commonly used for early screening of PCa. <sup>5</sup>Therefore, the effective use of PSA is worthy of further study by clinicians. Some scholars studied the postoperative specimens of 846 patients undergoing transurethral resection of Prostate and found that PSA may be helpful for risk stratification of early localized PCa and conservative treatment of patients. 64-10 ng/mL as TPSA gray area has been proposed for a long time, and many

related studies have been conducted. It has been reported that F/TPSA is beneficial to the diagnosis of PCa in grey area. 7Some scholars have also shown that prostate health Index (PHI) is closely related to the aggressiveness of PCa, and PHI has a good diagnostic effect for PCa whose PSA is in the gray area.8 It was found that the Prostate Imaging Reporting and Data System (PIRADS V2) was significantly correlated with pathology of biopsy, and PIRADS V2 helped in the diagnosis of PCa in the gray area of PSA.9 At present, most of the normal reference values of PSA used in China are still directly quoting the conclusions of foreign studies. However, considering the differences in race, diet, living habits, and diagnosis and treatment level between China and the Western countries, we cannot directly copy the research conclusions of western countries on PSA.<sup>10</sup> Studies have mentioned that ethnic differences may lead to different relationship between PSA and biopsy results, and the application scope of PSA value and F/T PSA in western countries may be different from that in China. F/TPSA is worthy of further study when PSA10-20 ng/mL.11

Trans-rectal Ultrasound guided biopsy of the prostate is the gold standard for the diagnosis of PCa, and there are many studies related to it.12-13 However, invasive procedures not only bring pain to patients, but also may cause complications related to biopsy. Therefore, in recent years, more and more studies have been conducted on individualized biopsy schemes. It has been reported that it is feasible to develop individualized biopsy plan combining PSA and prostate ultrasound findings. 4 Studies have shown that prostate volume has a significant impact on biopsy results. The larger the prostate volume, the lower the biopsy positive rate, and additional core of needle number can improve the positive rate.14 Some domestic scholars combined age, prostate volume, MRI and anal examination to study the four indicators, and the result showed that this method is conducive to the selection of biopsy timing and thus reduce unnecessary biopsy. 15 By analyzing the screening Group PSA, this paper aims to make the biopsy of patients with suspected PCa in Chengde area which may be more individualized. Previous studies have shown that patients with negative first biopsy

should be comprehensively evaluated according to imaging findings after excluding non-cancer factors leading to the increase in PSA level, so as to reduce the rate of missed diagnosis. 16 In this study, the influence of temporal heterogeneity and tissue heterogeneity caused by PCa on the outcome of biopsy was not considered. PSA≥4ng/ mL and F/TPSA < 0.16 (Group I) were correlated with biopsy results ( $\chi$ 2 =40.00, P < 0.05). When PSA≥10ng/mL and F/TPSA < 0.16 (Group II), there was also a correlation with biopsy results ( $\chi$ 2 =50.11, P < 0.05). The chi-square value of Group II was significantly higher than that of Group I, indicating that Group II had a stronger correlation with prostate biopsy results. The sensitivity, specificity, positive predictive value and diagnostic coincidence rates of Group I and Group II were 87.50%, 74.03%, 63.63%, 78.63% and 75.00%, 89.61%, 78.94% and 84.62%, respectively. Under different TPSA intervals, F/T<0.16 has different diagnostic efficacy for PCa. Group I is more sensitive and suitable for early screening. The earlier PCa is detected, the better the prognosis is, and the sensitivity of Group I is high. Therefore, biopsy diagnosis is more necessary when PSA≥4ng/mL and F/TPSA < 0.16, but the specificity of this ranges is low, the biopsy workload will increase, and the incidence of biopsy related complications will also increase. The specificity, positive predictive value and diagnostic coincidence rate of Group II were all higher than that of Group I, and patients in this interval had more biopsy value, which could improve the positive rate of biopsy. There are many ethnic groups and vast area in China, so the results of this study are expected to bring some reference value.

In short, with Group I as a reference, high sensitivity can reduce missed diagnosis, but it will increase the biopsy workload and the risk of biopsy related complications. Moreover, the adverse emotions such as fear and anxiety can not be excluded from reducing compliance. The specificity of Group II is stronger, the biopsy value is higher, and the biopsy positive rate is higher. Therefore, clinicians should conduct individualized biopsy according to patients' aspiration for biopsy, and actively conduct prostate MRI scan, bone scan and other auxiliary examinations for screening

when patients meeting Group I refuse biopsy, so as to strengthen the secondary prevention of PCa as much as possible. Compared with Group I, selecting Group II for biopsy can help clinicians make more patient-friendly decisions, reduce the workload of biopsy and reduce the incidence of complications related to biopsy.

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