Comparison of the diagnostic efficacy between transrectal prostate biopsy and transperineal cognitive fusion biopsy

Zhilei Zhang
Affiliated Hospital of Medical College Qingdao University
Fei Qin
Affiliated Hospital of Medical College Qingdao University
Wei Jiao
Affiliated Hospital of Medical College Qingdao University
Xuecheng Yang
Affiliated Hospital of Medical College Qingdao University
Yujun Li
Affiliated Hospital of Medical College Qingdao University
Yanxia Jiang
Affiliated Hospital of Medical College Qingdao University
Dapeng Hao
Affiliated Hospital of Medical College Qingdao University
Jie Li
Affiliated Hospital of Medical College Qingdao University
Ruizhi Zhou
Affiliated Hospital of Medical College Qingdao University
Mingxin Zhang
Affiliated Hospital of Medical College Qingdao University
Haitao Niu (niuhtqyfy123@126.com)
Affiliated Hospital of Medical College Qingdao University

Research

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Abstract

Background: This study aimed to compare the detection efficacy of transrectal ultrasound -guided systematic prostate biopsy (TR-SB) and transperineal cognitive fusion targeted +systematic biopsy (TP-SB+COG-TB) in patients with suspected prostate cancer (PCa). In addition, the relative clinical characteristics of PCa were evaluated. Methods: 385 patients were enrolled in this study, who underwent transrectal (n=275) or transperineal (n = 110) cognitive fusion biopsy. Relative factors of PCa including age, prostate volume and PSA level were collected for multivariable analysis. The cancer detection rates were compared, and logistic regression was used to assess the impact of patient characteristics on PCa detection Results: For all patients, the overall detection rates of TR-SB and TP-SB+COG-TB were 121/275(40%) and 67/110（60.91%）, respectively. TP-SB+COG-TB detected a higher rate of PCa (P =0.003) and more clinically significant prostate cancers (csPCa) (P=0.001) than TR-SB. Logistic regression analyses revealed that age、TPSA（total prostate specific antigen）and PV were related to the detection rate of PCa (P≤0.05). Conclusion： TP-SB+COG-TB could find more clinically significant PCa than TR-SB. Due to the high detection rate at certain ages, PSA levels and PV, patents' clinical characteristics should be considered in biopsy.

1. Background

Prostate cancer is a tumor with a high incidence of urinary system [1], especially in the male of European and American area. Approximately 1276,106 new prostate cancer cases (7.1%) were diagnosed globally in 2018, making it the third most common of all tumors[2]. Prostate biopsy is the gold standard for the diagnosis of prostate cancer, and both transperineal and transrectal biopsy guided by ultrasound have been the main approaches for prostate biopsy for decades[3]. However, which method is better is still under discussion[4].

With the multiparametric magnetic resonance imaging (MRI) in showing suspicious lesions widely used, the diagnostic accuracy of PCa could be increased[5]. Based on advances in MRI, a series of fusion biopsy methods combining transrectal ultrasound (TRUS) have emerged. Targeted biopsy based on MRI soon appeared, Notably, fusion biopsy and in-bore MRI-guided targeted biopsy can detect disease at higher rates than systematic biopsy alone, study reported that combination of MRI and ultrasound could achieve a detection rate of 34%, which is higher than 27% solely detected by systematic biopsy[6]. However, the equipment or specialized software needed in fusion biopsy and in-bore MRI-guided biopsy are very expensive, so the cognitive fusion based on MRI is becoming feasible especially in hospitals with limited resources[7], but it requires proficient skills for the surgeon.

How to select the optimal biopsy approaches to fit the different clinical characteristics, such as patients with different age, PV, prostate-specific antigen (PSA) value and PSAD, has rarely been studied[8]. In our study, we compared the detection rate of prostate biopsy and assessed the ability of the detection rate of

csPCa by TR-SB and TP-SB + COG-TB, and explored one accurate biopsy to adopt patients with different characteristics.

2. Patients And Methods

2.1 Patients

We retrospectively enrolled 385 patients who underwent prostate biopsy between May 2019 and November 2019. Among these patients, 275 underwent TR-SB and 110 underwent TP-SB + COG-TB in our Hospital. The criterion for prostate biopsy included PSA level > 4 ng/ml or abnormal digital rectal examination findings and clinical suspicion of prostate cancer by digital rectal examination, TRUS and prostatic MR imaging (MRI). Clinically significant prostate cancer was defined as high-grade prostate cancer (Gleason score of ≥ 7 or ISUP ≥ 2), with the Gleason grading method based on the 2005 International Association of Urinary Pathology (International Society of Urological Pathology, ISUP). All patients underwent MP-MRI on a 1.5-T MRI or 3.0-T MRI, and patients had at least three triplanar T2-weighted sequences, diffusion weighted imaging (DWI)and apparent diffusion coefficient (ADC) values collected, The region of interest was identified on MRI by our surgeon during the preoperative preparation. This study was approved by the Ethic Committee of the Affiliated Hospital of Qingdao University. All patients included were informed about the biopsy procedure, and written informed consent was obtained from every patient.

2.2 Patient characteristics

Age and baseline data including PSA level, PV and PSA density(PSAD), were collected. PV was measured by TRUS and calculated using the ellipsoid volume formula: PV (ml) = (π/6) × (anterior − posterior diameter [cm]) × transverse diameter (cm) × (superior − inferior diameter [cm]), PSAD was measured by PSA/PV.

2.3 Biopsy

For transrectal prostate system biopsy (TR-SB), the patients received the perioperative oral antibiotics (usually using levofloxacin/ceftibuten/baktar) for 3 days before the procedure. A biopsy gun (BARD MAXCORE/18*20; Bard, Tempe, USA) was used for the transrectal ultrasonography (bk3000; BK Medical Aps, Copenhagen, Denmark) with general intravenous anesthesia. Generally, systematic biopsies include 12–15 slices from the left and right lobes of the prostate[9]. The biopsy number might vary according to the prostate volume or additional suspicious transrectal ultrasound findings. The biopsy tissue was fixed in a separate glass bottle containing 10% formaldehyde solution. The patients were instructed to drink more water after the operation, and to continue to take oral antibiotics 2 ~ 3 d. At the same time, the postoperative reactions of the patients were closely observed. If abnormal complications (hematuria, urinary retention, fever, etc.) were found, the patients should be treated properly.

For transperineal cognitive fusion targeted + systematic biopsy (TP-SB + COG-TB), the patients were placed in the lithotomy position. Under the transrectal ultrasonography guidance (bk3000; BK Medical

Aps, Copenhagen, Denmark), the biplane prostate probe (Prostate Biplane E14C4t/4 MHz; BK Medical Aps) was introduced for localization, and local anesthesia or intravenous general anesthesia was administered to the TP patients. Local anesthesia with a peri-prostate nerve block effect (TP: LA + PPNB) was conducted with a long gauge needle[10]. COG-TB was first performed based on the images of MRI images taken preoperatively,and approximately 2 to 4 samples were taken from each suspicious lesion[11]. Systematic biopsy was typically 12–14 cores collected in the medial and lateral aspects of the apical, mid, and base of the prostate on the left and right side, and no perioperative antibiotic treatment was needed during the biopsy.

2.4 Statistics

The data were analyzed by IBM SPSS Statistics ver. 22.0 (SPSS Inc., Chicago, IL), Student t-test was used to compared the basical characteristic data between the two groups. The detection rates were analyzed by the chi-square test, Fisher's exact test and the Mann-Whitney U test accordingly. A logistic regression model for analyzing the effects of patients' clinical characteristics on the prostate cancer detection rate under TR and TP was constructed. All P values were two-sided, and a difference of $P < 0.05$ was considered statistically significant.

3. Results

3.1 Patient characteristics

The overall detection rate of PCa and basic clinical data of the patients are shown in Table 1. In the TR-SB group, the detection rate of PCa was 40% (121/275). In the TP-SB+COG-TB group, the detection rate of PCa was 60.91% (67/110). The overall PCa detection rate between the TR-SB group and TP-SB+COG-TB group was significantly different (P=0.003). The patients' clinical characteristics, including age, PSA level, PV and Gleason score of PCa, were not significantly different between the two groups (P≥0.05).

3.2 Prostate cancer detection rate stratified by age and prostate-specific antigen value

The stratified detection rates are listed in Table 2 and Table 3. The detection rate of TP-SB+COG-TB was higher than that of TR-SB for patients aged 60–80 years (56.81% vs 41.51%, P = 0.015). For patients with PSA levels of 10.0–20.0 ng/ml, the detection rate of TP-SB+COG-TB was higher than that of TR-SB (58.26% vs 24%, P=0.00024). Regarding patients with PV□50 ml, the detection rate of TP-SB+COG-TB group was higher than that of TR-SB (48.78% vs 30%, P=0.038), and the detection rate between the two groups was comparable in the stratification of PSAD. Regarding patients with PSAD≥0.2, the detection rate of TP-SB+COG-TB was higher than that of TR-SB (77.63% vs 59.91%, P=0.001).

3.3 Detection rates of prostate cancer and csPCa

Table 3 and Table 4 showthe bioptic Gleason score of the PCa patients in each group. In comparing the distribution of Gleason scores between TR-SB and TP-SB+COG-TB, TP-SB+COG-TB found more PCa in patients (GS=4+3) than the group of TR-SB (19.4% vs 7.02%, P=0.012). However, there was no difference in the detection rate regarding the distribution of GSs between the two groups (P=0.912). The percent of PCa patients with a Gleason score≤7 was 17.54% for the TR-SB group and 10.45% for the TP-SB+COG-TB group. PCa patients with a bioptic Gleason score ≥7 accounted for 88.59% of the TR-SB group and 89.55% of the TP-SB+COG-TB group. For all the patients, TP-SB+COG-TB detected more PCa patients with Gleason score ≥7 PCa than TR-SB detected (P =0.001).

Table 5 displayed the DR of csPCa of the different PSA interval between TP-SB+COG-TB and TR-SB, In the PCa patients with PSA (10-20 ng/ml), the proportion of patients with bioptic Gleason score ≥7 was 17% for the TR-SB group and 58.26% for the TP-SB+COG-TB group(P=0.001). For other PSA interval, there was no difference of DR of csPCa between two groups.

3.4 The effects of patients' clinical characteristics on the prostate cancer detection rate

Table 6 and Table 7 show the logistic regression analysis results of the effects of patients' clinical characteristics on the prostate cancer detection rate. Patients' PSA level and PV were found to be independent predictors of the detection rate in both in the TR-SB and TP-SB+COG-TB groups. Age was an predictor for the DR only in the TR-SB group. Patients who underwent two biopsies with higher PSA were inclined to have a higher detection rate (TP-SB+COG-TB, β=0.026, OR 1.027(1.007-1.046), P=0.007; TR-SB, β= 0.024,OR 1.025(1.015-1.035), P=0.0000054). and A similar effect of PV was discovered between the two groups (TP-SB+COG-TB, β=-0.016, OR 0.984(0.97-0.998), P=0.023; TR-SB, β-0.015, OR 0.985(.0977-0.993), P=0.000307).

4. Discussion

Prostate cancer is a common and high incidence rate disease in men worldwide. The early detection and diagnosis of prostate cancer can enable patients to obtain timely treatments and prolong their life[12]. Currently, the screen of prostate cancer is mainly performed by serum PSA, rectal ultrasound and MRI guided prostate biopsy. Our study is aimed to compare the detection rates of PCa and csPCa between two approaches of prostate biopsy.

Since Hodge first proposed transrectal ultrasound prostate biopsy to diagnose prostate cancer in 1989, since then Prostate biopsy is the gold standard approach to verify prostate cancer diagnosis [13]. Studies have shown that the detection rate of traditional transrectal prostate biopsy was only 57.5%[14], but it was still used in the clinic due to its advantages, such as its convenient operation, short operation time, and low cost. Traditional ultrasound guided prostate biopsy is a nonspecific biopsy of all regions within the

prostate; in particular, it is difficult to identify and accurately locate the echo sound prostate cancer tissue, it was also hard to confirm the clinically significant prostate cancer lesions[15].

With developments of mpMRI, more suspected prostate cancer cases were have been diagnosed. For MRI-TRUS cognitive fusion, mpMRI examination was firstly conducted to obtain images of the prostate gland tissue under different sequences[16], Then, with the help of a radiologist, suspected lesions were performed underwent TRUS prostate biopsy. The suspected lesions were located accurately by mpMRI along with the convenience of ultrasonic examination, so this method could significantly improve the positive rate of biopsy and the detection rate of prostate cancer[17].

Our respective study included 385 patients, 110 patients underwent TP-SB + COG-TB and 275 patients underwent TR-SB. The detection rate of TR-SB was 40%,which was lower than the 57.5% reported in the literature. Usually, TR-SB and TP-SB are two approaches of prostate biopsy operations, and previous studies revealed that differences in the overall PCa detection rate between the two biopsy methods was comparable[18]. However, the DR of TP-SB + COG-TB was 60.91%, which was higher than 57.5%, so TP-SB + COG-TB was a more effective diagnostic strategy for PCa. The DR between the two groups was significantly different in our study, which suggested that the accuracy of transperineal MRI guided cognitive fusion prostate biopsy to diagnose prostate cancer was significantly improved, which was consistent with the findings Moore reported[19]. This finding indicated that to some extent, the higher detection rate may be attributable to the MRI directed biopsy, which suggested that MRI-guided cognitive biopsy was meaningful and more accurate. It also indicated that the prostate suspected lesion on MRI was more apparent than that on ultrasound, showing the value of targeted biopsy. some previous studies addressed that the positive results of systematic biopsy combined with targeted biopsy were more precise than those of targeted biopsy alone.

Our study also compared the DR of patients with different clinical characteristics in order to guide surgeons' decision making regarding the appropriate method of prostate biopsy, which could reduce negative results and decrease repeated biopsies, which may ultimately reduce the pain and financial costs of the patients. The study assessed the prostate cancer detection rate stratified by age, prostate-specific antigen value, prostate volume and PSAD.

First, it is well known that prostate cancer mainly occurs in older men, and patient age is the most important factor considering whether a patients is able to tolerate the operation or not, since in general, elderly patients are associated with basic diseases, A previous study showed that PCa was discovered in 30.5% of patients aged > 75 years compared with 5.2% in the patients aged < 50 years[20]. The detection rate of prostate cancer in our study increased with age. Additionally, we found that TP-SB + COG-TB had a higher DR than TR-SB for patients aged(60–80) years($P = 0.015$), and the number of patents aged (60–80) years in our study was the largest among all patients. To some extent, the DR of TP-SB + COG-TB was more credible. The logistic regression results of the two biopsy methods showed that patient age had a positive correlation with the total of DR, but there was no significant difference between TP-SB + COG-TB and TR-SB, which further suggested the superiority of TP-SB + COG-TB.

The PSA level is the most widely used factor for prostate cancer screening. Generally, When TPSA exceeds 4 ng / mL, a prostate biopsy needs to be done, however, numerous factors including age, diet, race, genetic variation, prostate volume and nonmalignant diseases can easily affect the PSA level[21]. Therefore, we combined the PV to predict the DR of PCa. The data of these two factors were also relevant to the DR of PCa, The PSA level was positively correlated, while prostate volume was negatively correlated with the DR of PCa. For patients with PSA levels of 10–20 ng/ml, PV ≥ 50 ml and PSAD ≥ 0.2, there was a significant difference in the diagnostic efficacy between the two groups. Another study reported that the detection rate of systematic biopsy was 36.5% among those with PSA levels of 10.0–20.0 ng/ml[22]. The DR of the TP-SB + COG-TB group was 58.26% much higher than previous reported, and a similar result was found for patients with PV ≥ 50 ml. This finding may be partly because in these patients, tumors located in the anterior or apical prostate would usually be missed by systematic TRUS-Bx, while prebiopsy MRI could discover these suspect lesions in prostate, which may potentially lead to increase the cancer detection, and also be attributed to more accurate Gleason score, this may especially be benefit with large prostate volumes.

csPCa was defined as a biopsy sample with Gleason score ≥ 7 or IUSP (international society of urological pathology) ≥ 2. Attaining one good biopsy to diagnose csPCa has a great significance and can avoid repeated biopsy and reduce the overtreatment, especially for patients aged ≥ 80 years with or without chronic disease and PSA levels in the grey area (4–10 ng/ml). Our study compared the detection rate of csPCa among different PSA levels. The approach of TP-SB + COG-TB found more csPCa among all PSA levels than TR-SB, and there was a great difference between them in the PSA level ranged 10 to 20 ng/ml. The distribution of the Gleason score and the percent of csPCa between the two approaches were also compared and showed no discrepancy, However, we found that the total rate of csPCa in the TP-SB + COG-TB group was higher than that in the TR-SB group, This was a better indication that TP-SB + COG-TB was superior for finding more clinically significant prostate cancers, which should mostly be attributed to MRI-guided cognitive targeted biopsy (TB). A previous study supported that MRI-TB could discover more prostate cancers with the aid of MRI[23],of course, TB needed to be combined with SB due to the false-negative predictive rate for mpMRI in detecting csPCa, systemic biopsy could detect suspicious lesions not shown on mpMRI[24]. The risks of csPCa have been predicted by several nomograms based on mpMRI, making it easier to decide whether to perform the biopsy or not [25, 26]. Our approach of TP-SB combined with COG-TB required the surgeon to be proficient in reading the mpMRI results, which may slightly decrease the DR of csPCa to a certain extent for the subjectivity. Overall, according to our study results, we showed that TP-SB + COG-TB has detected more clinically significant PCa with a better diagnostic efficiency than TR-SB.

There were also some certain limitations of our study. First, this was a retrospective study, and the number of patients was small, Second, the rectal ultrasound probe could induce the prostate gland to be compressed, so it could not completely match the prostate scanned by MRI, which may cause certain errors. It was difficult to accurately puncture very small lesions. This method was highly dependent on MRI technology and the knowledge of the radiologist and surgeon, which may exist some certain

subjectivity, and it would affect the accuracy. Cognitive biopsy requires the professional training of the surgeon and a long time learning cycle. Third, our study did not include the postoperative complications, which are also an important part of prostate biopsy we should think about.

Conclusions

The data of this study suggested that TP-SB+COG-TB biopsy could attain higher detection rate of PCa and more csPCa than TR-SB by systematic biopsy alone, especially for patients aged 60-80 years with PSA levels of 10-20 ng/ml and large volume prostate cancer. Moreover, regardless of which prostate biopsy is performed, the clinical characteristics of the patient, such as age, PSA and PV should be taken into account, as they were associated with the prostate cancer detection rate, and age had a greater significance on the PCa detection rate of TR-SB than TP-SB+COG-TB. With regard to csPCa, TP-SB+COG-TB had a higher detection rate of clinically significant PCa than TR-SB alone.

Declarations

Ethics approval and Consent for participate: This study was approved by the Ethic Committee of the Affiliated Hospital of Qingdao University. Informed consent was obtained in both written and verbal format from patients to participate.

Consent for publication; Informed consent was obtained in both written and verbal format from patients to publish.

Availability of data and material: Records and data pertaining to this study are in the patient's secure medical records in the Affiliated Hospital of Qingdao University

Competing interests: Not applicable

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Authors' contributions (ZL Zhang: Data Collection, Manuscript writing; F Qin: Data Collection; W Jiao and XC Yang: project development; YJ Li and YX Jiang: Pathological diagnosis; DP Hao and J Li: Imaging diagnosis RZ Zhou: Imaging Technology Support; MX Zhang and HT Niu: made supervision and helped. reviewing the manuscript)

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Abbreviations

PCa: prostate cancer, TP-SB+COG-TB: transperineal cognitive fusion targeted +systematic biopsy, TR-SB: transrectal ultrasound-guided systematic prostate biopsy, csPCa: clinically significant prostate cancer, TPSA: total prostate specific antigen

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Tables

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