A Prospective Study Comparing Cancer Detection Rates of Transperineal Prostate Biopsies Performed by Junior Urologists versus a Senior Consultant in a Real-World Setting

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Abstract

Introduction: Prostate biopsy (PB) is a typical daily practice method for the diagnosis of prostate cancer (PCa). This study aimed to compare the PCa detection rates and peri- and postoperative complications of PB among 3 residents and a consultant. Patients and Methods: A total of 343 patients who underwent PB between August 2018 and July 2019 were involved in this study. Residents were systematically trained for 2 weeks by a consultant for performing systematic biopsy (SB) and targeted biopsy (TB). And then, 3 residents and the consultant performed PB independently every quarter due to routine rotation in daily practice. The peri- and postoperative data were collected from a prospectively maintained database (www.pc-follow.cn). The primary outcome and secondary outcome were to compare the PCa detection rates and complications between the residents and consultant, respectively. Results: There was no significant difference between the residents and consultant in terms of overall PCa detection rates of SB and TB or further stratified by prostate-specific antigen value and prostate imaging reporting and data system (PI-RADS) scores. We found the consultant had more TB cores (175 cores vs. 86–114 cores, \( p = 0.043 \)) and shorter procedural time (mean 16 min vs. 19.7–20.1 min, \( p < 0.001 \)) versus the residents. The complication rate for the consultant was 6.7% and 5%–8.2% for the residents, respectively (\( p = 0.875 \)). Conclusions: The residents could get similar PCa detection and complication rates compared with that of the consultant after a 2-week training. However, the residents still need more cases to shorten the time of the biopsy procedure.

Introduction

Prostate cancer (PCa) is a common cancer in men. In 2018, there were >1.27 million new cases and 359,000 associated deaths worldwide, which makes it the second most frequent cancer and the fifth leading cause of cancer death in men [1]. Prostate biopsy (PB) is an important method for diagnosing and further staging. Currently, the
most widely used biopsy method is 12-core system biopsy (SB). However, underdiagnosis and undertreatment occur because of the errors of sampling and grading [2]. The false-negative rate of SB is 11–13% [3, 4]. It also has the limitations of overdiagnosis to the patients with low-risk cancers [3]. Multiparametric magnetic resonance imaging (mpMRI) is more sensitive than the ultrasound-guided prostate biopsy (TRUS biopsy) in clinically significant cancer (csPCa) [5]. And, MRI-targeted biopsies (TB) can improve the detection in high-grade cancers [6–8].

The main approaches of TB include cognitive fusion (COG-TB), software-based fusion (FUS-TB), and in-bore or in-gantry TB (IB-TB), which are performed either by freehand or using a brachytherapy grid [9]. They have similar detection rates in overall or csPCa [10] and are all better than SB in csPCa [11–13]. Though TB is better than SB in diagnosis [6], patients who underwent both SB and TB have higher detection rates [14]. So, combined MRI-target and systematic biopsies (CB) are reported to get better effects. CB have higher detection rates and less error in upgrades than with either method alone [7, 14]. Several studies have investigated the learning curve of both SB and TB. Kasabwala et al. [15] found the detection rates of the TB increased after 98 cases and the decrease in fibromuscular tissue in SB after 84 cases. The time of the TB also shortened after training for cases [16, 17].

Professional skills and rich experience are required to ensure high detection rates in CB. But how long a resident needs to master this procedure is unknown. Three residents were trained by an experienced consultant for SB and TB for 2 weeks of systematic training schedule. This study prospectively investigated the PCA detection rates and peri- and postoperative complications of PB among the 3 residents and the consultant.

Materials and Methods

Prostate Biopsy Training Pattern

Three junior residents (A, Shu-xiong Zeng; B, Bi-ming He; and C, Guan-yu Ren) received systematic training by the consultant (Hai-feng Wang) for PB. The consultant had >20 years of urological experience and performed >2,000 PB with SB, TB, and CB techniques. The junior residents had 2–3 years of urological experience and had the training course for PB directed by the consultant for 2 weeks in a row. The training arrangement is shown in Figure 1, and each resident initially began with local anesthesia and then performed SB for patients under the supervision of the consultant, thereafter followed by cognitive mpMRI and ultrasound fusion TB. During the training course, every resident independently performed 20–30 PB including SB and CB techniques under the supervision of the consultant. Residents would qualify for PB when they met the standard of identifying suspicious lesions from mpMRI and ultrasound, became skilled with the procedures of PB, and were familiar with how to manage potential complications after PB.

Study Cohort

From August 2018 to July 2019, clinical and pathological information of patients who underwent PB in Shanghai Changhai Hospital was prospectively maintained in our database (www.pc-fol-low.cn). During this time period, the consultant and 3 junior residents independently performed PB for every 3 months due to routine rotation in clinical practice. Patients who had indications for PB were consecutively included and assigned to the urologists’ PB according to the time of hospitalization, and thus the patient cohort represented the real-world clinical practice setting. We screened for patients who underwent PB performed by these different urologists, and the exclusion criteria were patients who underwent general anesthesia for PB or patients who had received prior therapy for PCa. Written informed consent was obtained from each patient in this study. This study protocol was approved by the Ethical Board of Changhai Hospital and was performed in accordance with the ethical guidelines outlined in the Declaration of Helsinki.

Patient Management

Indications to perform PB included elevated prostate-specific antigen (PSA), abnormal total/PSA-free-PSA ratio, abnormal digital rectal examination, positive mpMRI (prostate imaging reporting and data system, PI-RADS ≥3), or regular MRI (lesions suspected on MRI which only had the T1-weighted and T2-weighted imaging sequences). Indications to have mpMRI examination prior to PB or following a previous negative PB in our center were at the referring urologist’s discretion. Some patients already had mpMRI or regular MRI in other hospitals before referred to our center for PB. All patients had undergone SB. Patients with suspicious lesions on mpMRI or MRI underwent PB. We also performed TB for patients with suspicious lesions identified by ultrasound images. Patients were excluded for analysis if they had any prior therapy for PCa, asked for a certain urologist for PB, or required PB under general anesthesia. We used the numeric rating scale (NRS) of pain which was a scale ranging from 0 to 10, with 0 representing no pain and 10 representing unbearable pain. The patients chose a number to describe the pain immediately after biopsy.

Biopsy Technique

Oral levofloxacin was administered once daily starting the day before the procedure. PB were performed under the guidance of an ultrasound device (Flex focus 800; BK Ultrasound, Peabody, MA, USA), equipped with a bi-planar transrectal transducer (8848; BK Ultrasound, Peabody, MA, USA) under local anesthesia [18]. We used a biopsy gun (Magnum MG15-22; Bard, Tempe, AZ, USA) equipped with a biopsy needle (18G, 130; Bard) to perform the biopsy procedure. The SB region was described previously [19]. TB were done using freehand without any other auxiliary tools. Three cores were taken for each suspicious lesion. The details of the biopsy procedure were shown in our previous study [20].

End Points and Statistical Analyses

The primary outcomes were the overall PCA detection rates of PB. The secondary outcomes were PCA detection rates stratified by SB and TB approach, PSA level, and PI-RADS scores; the complications dur-
ing or after PB; and self-reported numeric pain rating scale. Data were analyzed using SPSS 22.0 (IBM, Armonk, NY, USA). Categorical data were compared between groups using the χ², continuity correction, or Fisher’s exact test, while continuous data were compared by analysis of variance or the Kruskal-Wallis H test. All p values were 2-sided, and a difference of p < 0.05 was considered statistically significant.

Results

Three junior residents were trained through the mentioned training mode for 2 weeks in advance by the same consultant before performing the biopsy independently (Fig. 1). Biopsies were performed by 1 consultant and 3 junior residents independently every quarter from August 2018 to July 2019. In total, 343 patients were identified as suitable for inclusion in the study. Twenty-five patients were excluded for general anesthesia, and 31 patients were excluded for prior local therapy for PCa.

Patient Characteristics

The median age of the entire cohort was 67.25 years old, and the median PSA was 11.89 ng/mL. The consultant and 3 residents performed 90, 85, 88, and 80 transperineal prostate biopsies, respectively. Clinical characteristics of the patients in each group are shown in Table 1. There were no significant differences amongst groups in terms of age, PSA levels, the rate of patients who underwent mpMRI, and comorbidity.

Detection Rates of Prostate Cancer

As shown in Table 2, procedural time was significantly shorter for the consultant versus residents (mean 16 min vs. 19.7–20.1 min, p < 0.001). The proportions of PCA-positive biopsy were similar among the consultant and 3 residents. The detection rates of PCA were 61.1%, 54.1%, 58.0%, and 52.5% for the consultant and 3 residents, respectively (p = 0.733). Specifically, when stratifying the approach of biopsy...
as SB and TB, there were no statistically significant differences for the PCA detection rates for the consultant and 3 residents. As for the number of TB cores, the consultant had performed more TB cores compared with those of the residents (175 cores vs. 86–114 cores, \(p = 0.043\)) because there were more suspected lesions by mpMRI or ultrasound in the consultant group. However, there were no significant differences in the rates of PCA-positive TB cores between the consultant and residents (43.4% vs. 47.4%–55.8%, \(p = 0.224\)). As for TB for lesions suspected by the urologists but with PI-RADS <3, the positive rates were 1/6 (16.7%), 0/2 (0.0%), 1/4 (25.0%), and 2/6 (33.3%) for the A–C residents and consultant, respectively. The biopsy results of Gleason scores were summarized in online supplementary Table 1 (see www.karger.com/doi/10.1159/000518493 for all online suppl. material). No obvious difference in Gleason scores was identified between the consultant and residents. Biopsies performed by the consultant yielded the rates of Gleason ≥3 + 4 of 55.6%, and the rates of residents ranged from 46.3% to 53.4% (\(p = 0.568\)).

Table 3 presents the PCA detection rates of systematic and targeted biopsy further stratified by PSA value, and there was no statistical difference in the detection rate for PCA in different levels of PSA between the consultant and residents. The only significant difference was captured for SB at a PSA value between 20 and 100 ng/mL between resident A and resident

| Table 1. Patient characteristics |
|---------------------------------|
|                                | Resident A | Resident B | Resident C | Consultant | \( p \) value |
| Sample size                    | 85         | 88         | 80         | 90          |              |
| BMI                            | 24.61±3.09 | 23.98±2.93 | 24.58±2.74 | 24.33±2.68 | 0.440        |
| Age, years (range)             | 67.32±9.18 (39–89) | 67.51±7.44 (45–84) | 66.54±7.84 (47–84) | 67.57±9.87 (41–87) | 0.792 |
| Median PSA, ng/mL (IQR)        | 10.97 (7.37–24.21) | 12.76 (7.55–31.37) | 11.92 (7.86–32.71) | 16.28 (8.40–51.00) | 0.311 |
| Cases had mpMRI, n (%)         | 33 (38.8)  | 32 (36.4)  | 26 (32.5)  | 46 (51.1)  | 0.071        |
| Positive mpMRI, n (%)          | 17 (20.0)  | 19 (21.6)  | 16 (20.0)  | 28 (31.1)  | 0.239        |
| Hypertension, n (%)            | 35 (41.2)  | 29 (32.95) | 33 (41.25) | 31 (34.4)  | 0.551        |
| Coronary heart disease, n (%)  | 2 (2.4)    | 4 (4.55)   | 1 (1.25)   | 2 (2.2)    | 0.629        |
| Diabetes, n (%)                | 5 (5.9)    | 7 (7.95)   | 9 (11.25)  | 7 (7.8)    | 0.653        |

IQR, interquartile range; PSA, prostate-specific antigen; mpMRI, multiparametric magnetic resonance imaging.

| Table 2. The outcome of prostate biopsies between groups of residents and consultant |
|-----------------------------------------------|
|                                | Resident A | Resident B | Resident C | Consultant | \( p \) value |
| Time of PB, min                  | 20.1±2.7  | 19.7±3.1  | 20.0±2.9  | 16.0±2.6  | <0.0001      |
| Overall positive rates of PB, % (\(N/n\)) | 54.1 (46/85) | 58.0 (51/88) | 53.8 (43/80) | 61.1 (55/90) | 0.733        |
| Positive rates of SB             | 54.1 (46/85) | 58.0 (51/88) | 52.5 (42/80) | 61.1 (55/90) | 0.666        |
| Positive rates of TB             | 52.9 (18/34) | 64.3 (18/28) | 57.1 (16/28) | 51.0 (25/49) | 0.707        |
| Positive rates of TB cores, % (\(N/n\)) | 47.4 (54/114) | 55.8 (48/86) | 52.9 (46/87) | 43.4 (76/175) | 0.224        |
| Positive rates of TB with different MRI approach, % (\(N/n\)) | 52.2 (12/23) | 66.7 (12/18) | 64.7 (11/17) | 55.6 (20/36) | 0.736        |
| With mpMRI**                     | 54.5 (6/11) | 60.0 (6/10) | 45.5 (5/11) | 38.5 (5/13) | 0.740        |
| Positive rates of TB with PI-RADS stratification, % (\(N/n\)) | 64.7 (11/17) | 75.0 (12/16) | 76.9 (10/13) | 75.0 (18/24) | 0.886        |
| 3                               | 66.7 (2/3) | 40.0 (2/5) | 60.0 (3/5) | 33.3 (2/6) | 0.805        |
| 4                               | 55.6 (5/9) | 83.3 (5/6) | 83.3 (5/6) | 88.9 (8/9) | 0.442        |
| 5                               | 80.0 (4/5) | 100.0 (5/5) | 100.0 (2/2) | 88.9 (8/9) | 1.000        |
| Positive rates of TB with PI-RADS <3*, % (\(N/n\)) | 16.7 (1/6) | 0.0 (0/2) | 25.0 (1/4) | 33.3 (2/6) | 0.085        |
| Median NRS (IQR)                | 2.00 (0.00–3.00) | 2.00 (1.00–3.00) | 1.50 (0.25–2.00) | 2.00 (1.00–3.00) | 0.164        |

PB, prostate biopsy; SB, systematic biopsy; TB, targeted biopsy; PI-RADS, prostate imaging reporting and data system; mpMRI, multiparametric magnetic resonance imaging; NRS, numeric rating scale; IQR, interquartile range. * The patient with PI-RADS <3 still received TB because other indications for PB existed such as elevated PSA, abnormal total-PSA/free-PSA ratio, or abnormal digital rectal examination. ** Several patients with negative mpMRI or regular MRI reported by radiologists still underwent TB if lesions were suspected by the urologists.
Further analysis revealed more patients underwent mpMRI at a PSA value of 20–100 ng/mL in resident A group compared with resident B group (5 vs. 2, \( p < 0.001 \)), which suggested mpMRI might contribute to the detection of suspected lesions in SB. There was no significant difference in the rate of PCa detection for TB of lesions with PI-RADS score \( \geq 3 \) in mpMRI between the consultant and residents (75.0% vs. 64.7–76.9%, \( p = 0.886 \)). The PCa detection rates of TB with different PI-RADS scores of mpMRI were also examined, and there was also no statistical difference among the consultant and residents (Table 3).

### Complications of Prostate Biopsy

As shown in online supplementary Table 2, the complications were hematuria, fever, urinary retention, and vasovagal reactions. The overall complication rates for the consultant was 6.7% and 5–8.2% for the residents (\( p = 0.875 \)). Notably, the most frequent collateral event was hematuria of varied degrees, which occurred for nearly all patients at the first urination after biopsy and could resolve spontaneously. Only those patients with obvious gross hematuria after biopsy and managed with placement of a catheter at the discretion of urologists to prevent formation of blood clot in the bladder were recorded. Two patients had fever over 38.5°C within 24 h after biopsy and were treated with intravenous antibiotics. Three patients suffered from urinary retention and were managed with an indwelling catheter for 5–7 days and took tamsulosin orally once a day. There were 13 patients who experienced vaso-vagal reactions with symptoms of low blood pressure within 30 min after biopsy, and all of them recovered with continuous blood pressure monitoring and rest on bed. In terms of self-reported pain scale, there was no significant difference in NRS between the consultant and resident groups (\( p = 0.085 \)).

### Discussion

Digital rectal examination, PSA levels, imaging, and biopsy are the basic screening methods for the prostate diseases [8]. PB are the gold standard for diagnosis of PCa. Early diagnosis of csPCa will make the health care easier and reduce the death rate. In the last decade, mpMRI was used to locate and target the suspicious area to decrease the cores needed in SB. TB and CB have become new methods in detecting PCa. Ahdoot et al. [7] investigated 2103 patients with PCa and demonstrated that the detection rates of TB and CB were 51.5% and 62.4%, respectively. CB detected 208 more cases than either SB or TB alone [7].

Prostate lesions are targeted mainly by COG-TB, FUS-TB, or IB-TB on MRI. Wegelin et al. [10] found there was no difference in detection rates of overall or csPCa among the 3 approaches in a randomized controlled trial. The biopsy can be done by freehand or using a brachytherapy grid transperineally or guided by transrectal ultrasound. Our previous study has shown that there was no difference between freehand and template-guided mapping biopsy in detection rates in either overall PCa or csPCa [19]. The grid is more user-friendly for less-experienced clinicians, but it is time consuming and expensive [9].

Experience is an important factor for the detection rates in TB, and the missed cases can be decreased with improved experience [21]. The novices do have a potential learning curve which would limit the detection accuracy in TB. Mager et al. [16] demonstrated the need for >63 biopsies to reach a steady level. And, Halstuch et al. [17] reported that shortening of surgical time and improvement in detection rates happen after 110–125 cases. However, it is still unknown how many PB junior urolo-

### Table 3. PCa detection rates of systemic and targeted biopsies stratified by the PSA value

| PSA Value | Resident A | Resident B | Resident C | Consultant | \( p \) Value |
|-----------|------------|------------|------------|------------|--------------|
| 0–10      | 10/40 (25.0) | 12/35 (34.3) | 10/32 (31.3) | 10/36 (27.8) | 0.832 |
| 10–20     | 10/18 (55.6) | 15/24 (62.5) | 11/20 (55.0) | 13/19 (68.4) | 0.807 |
| 20–100    | 17/18 (94.4) | 15/20 (75.0) | 14/21 (66.7) | 19/22 (86.4) | 0.135 |
| >100      | 9/9         | 9/9         | 7/7         | 13/13       | –             |

PCa, prostate cancer; PSA, prostate-specific antigen; SB, systematic biopsy; TB, targeted biopsy.
gists are needed to reach a comparable PCa detection rates as to experienced urologists.

In the present study, we found that a resident could get similar PCa detection rates in PB compared with that of the experienced consultant after a 2-week training schedule. Neither the total detection rates nor the csPCa (Gleason ≥3 + 4) detection rates had significant difference between the residents and consultant when PB were performed independently. Although the residents need a longer time to perform the PB procedures than the consultant, the resident group did not show higher complication rates and pain scores. Halstuch et al. [17] demonstrated a decreased surgical time from 45 min to 15 min after 109 cases with the transrectal approach and from 55 min to 18 min after 124 cases with the transperineal approach. Marra et al. [22] found that procedural time and severe anxiety were the risk factors for severe biopsy pain. An experienced clinician with practiced biopsy skills may reduce the procedural time and thus relieve the patient’s duration of anxiety, which resulted in less pain during the procedure. Shortened procedural time and less anxiety may also be of benefit to reduce the vaso-vagal reactions. Pavlin et al. [23] demonstrated that surgical procedure duration was independently associated with increased risk of vaso-vagal reaction. As a result, the residents still need more practice to become more skilled at biopsies.

Complication rate is another important parameter to evaluate a surgical procedure. The main complications of PB include infectious, hematuria, rectal bleeding or hemospermia, acute urinary retention, pain, vaso-vagal reactions, and erectile dysfunction [24]. In this study, we found no significant difference among groups in terms of complication rates after PB. The positive rates of PB were further analyzed by PSA stratification, and there was no statistically significant difference in the detection rates for PCa in different levels of PSA among groups. However, we found a statistically significant difference between resident A and resident C at a PSA value between 20 and 100 ng/mL in SB. Further analysis revealed that significantly more cases had mpMRI evaluation at a PSA level of 20–100 ng/mL in resident A group which might have contributed to this difference. This suggested that mpMRI might have better performance for identifying lesions than ultrasound in patients with 20–100 ng/mL PSA level in SB, as it has a higher detection rate in csPCa in TB.

There are still several limitations in our study. First, the sample size of patients and residents was relatively small, and further studies with larger sample size are warranted. Second, the patients were not assigned randomly, which might induce a selection bias. Third, it is controversial whether cognitive TB could achieve the same results as fusion TB with fusion software, and we use cognitive TB instead of fusion TB in the present study. Recently, the FUTURE trial demonstrated no significant difference between the 2 methods [10]. Finally, we mainly focused on the PCa detection rates of the PB as the primary outcome. Although we found the detection rates of PCa among groups were comparable, the procedure duration of PB in residents was still longer than that of the consultant. This suggests that more cases are still needed for the residents to get a further proficiency level.

Conclusions

The proposed 2-week TP PB training schedule is efficient, and residents could get a similar PCa detection rate for different PSA levels in both TB and SB or CB compared with that of the consultant. However, the residents still need more samples to shorten the time of the biopsy procedure.

Statement of Ethics

The Shanghai Changhai Hospital Ethics Committee (approval date: 2018/7) gave approval for this study. Written informed consent was obtained from each patient in this study.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

This research was financed by grants from the Qihang program of Naval Medical University, Shanghai Sailing Program (18YF1422700), Shanghai Pujiang Program (18PJDO58), and National Natural Science Foundation of China (81772720, 81572509, 81802515, 81801854, and 82172871), National Key Research and Development Program of China (No. 2019YFC0119100); Shanghai Pudong New District Health system Medical talents training plan, China (No. PWrd2020-17); Fund of Development on Science and Technology of Shanghai Pudong New District, China (No. PKX2020-S11); Shanghai ”Action Plan of Technological Innovation” (No.18441910900).

Author Contributions

C. Xu, X. Gao, S. Zeng, and H. Wang contributed to conceptualization. H. Li, G. Ren, H. Chen, J. Song, Z. Shi, S. Zeng, and B. He contributed to data curation. J. Song, S. Zeng, and B. He contribu-
uted to formal analysis. C. Xu and S. Zeng contributed to funding acquisition. Z. Shi, S. Zeng, B. He, H. Li, G. Ren, and H. Chen contributed to investigation. C. Xu, X. Gao, S. Zeng, and H. Wang contributed to methodology. C. Xu, X. Gao, S. Zeng, and H. Wang contributed to project administration. H. Li, G. Ren, H. Chen, Z. Shi, and S. Zeng contributed to resources. J. Song, S. Zeng, and B. He contributed to software. C. Xu, X. Gao, and L. Wang contributed to supervision. C. Xu, X. Gao, S. Zeng, and H. Wang contributed to validation. J. Song, S. Zeng, B. He, and H. Li contributed to visualization. J. Song, S. Zeng, and B. He contributed to writing – original draft. J. Song, S. Zeng, B. He, and X. Yu contributed to writing – review and editing. J. Song, B. He and H. Li have contributed equally to this work.

Data Availability Statement
The datasets used and analyzed in the current study are available from the corresponding author on reasonable request.

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