Original Article

Value of digital rectal examination in patients with suspected prostate cancer: a prospective cohort analysis study

Yidie Ying[1#], Wei He[1,2#], Qiao Xiong[1,3#], Ziwei Wang[1], Maoyu Wang[1], Qing Chen[1], Meimian Hua[1], Shuxiong Zeng[1], Chuanliang Xu[1]

[1]Department of Urology, The First Affiliated Hospital, Naval Medical University, Shanghai, China; [2]College of Basic Medical Sciences, Naval Medical University, Shanghai, China; [3]Department of Urology, Institute of Urology, West China Hospital, Sichuan University, Chengdu, China

Contributions: (I) Conception and design: S Zeng, C Xu; (II) Administrative support: S Zeng, C Xu; (III) Provision of study materials or patients: S Zeng, C Xu; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: Y Ying, W He, Q Xiong; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Shuxiong Zeng, MD, PhD; Chuanliang Xu, MD, PhD. Department of Urology, The First Affiliated Hospital, Naval Medical University, Changhai Road, Yangpu District, Shanghai 200433, China. Email: zengshuxiong@126.com; chuanliang_xu@126.com.

Background: Digital rectal examination (DRE) is a straightforward, cost-effective, practical, and time-honored physical examination method that plays a valuable role in the detection of prostate cancer (PCa). Nevertheless, with the advent of the prostate-specific antigen (PSA) era, the necessity of performing DRE has become a subject of debate. Our aim was to investigate the diagnostic efficacy and adjunctive role of DRE in a population (Prostate Imaging Reporting and Data System (PI-RADS), PI-RADS ≥3 or PSA ≥4 ng/mL) suspected of PCa.

Methods: Five hundred and ninety-seven patients with suspected PCa requiring referral for biopsy were prospectively enrolled consecutively from February 2020 to May 2021. All patients received DRE and corresponding clinical diagnosis by a urologist before biopsy. According to the collected clinical and pathological information, the diagnostic performance of DRE in different PSA stratifications, and its association with tumor location and Gleason score (GS) were statistically analyzed.

Results: Among patients with suspected cancer, the diagnostic accuracy of DRE was 63.45%. Compared with central zone or transition zone tumors, the recall rate of peripheral zone PCa with DRE-positive results was higher (65.50% *vs.* 34.55%). DRE-positive results were significantly correlated with GS ≥7 PCa (P<0.001), and the average GS of DRE-positive PCa patients was significantly higher than that of DRE-negative (7.92 *vs.* 7.11, P<0.001).

Conclusions: DRE may help physicians further judge the necessity of biopsy in patients with elevated PSA, and preliminarily estimate the location and invasiveness of the tumor. However, it is still necessary to explore the value of DRE in a normal PSA population.

Keywords: Prostate cancer (PCa); digital rectal examination (DRE); early detection of cancer; prostate-specific antigen (PSA)

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Introduction

Prostate cancer (PCa) is the second most common malignancy and the fifth leading cause of cancer-related death in men worldwide (1). The incidence of PCa in China is steadily increasing, and over the past 30 years, the disease burden caused by PCa has further escalated, indicating an unfavorable trend (2). PCa occurs mostly in older patients, more than one-half of the PCa occur in populations older

than 75 years old (3). The prognosis of late-stage PCa is poor and treatment options are limited, while early-stage, low-risk PCa can be treated with surgery or hormone therapy and achieve a good prognosis. Thus, the early detection of PCa is of utmost importance.

Serum prostate-specific antigen (PSA) and digital rectal examination (DRE) are commonly used clinical PCa standard screening tools (4,5). PSA is a marker that reflects the pathological changes in the prostate. Since its discovery in 1980, it has become a routine test for PCa. However, when PSA levels are in the "gray zone" of 4–10 ng/mL, the high false positive rate may lead to overdiagnosis and overtreatment of PCa. Some countries' health ministries, based on the current scientific evidence, do not recommend PSA-based screening for asymptomatic men (6). Moreover, PSA cannot accurately distinguish the risk levels of invasive disease, so it needs to be supplemented by improved screening methods (7,8).

DRE is a simple and inexpensive physical examination that is commonly used in routine urological practice. It is also a traditional method for screening PCa. However, the value of DRE has been increasingly challenged due to its potential drawbacks, such as causing fear, discomfort, and complications for the patients, as well as having low sensitivity for detecting PCa. Different guidelines have different recommendations for the use of DRE. In 2020, the European Association of Urology (EAU) guideline suggested that DRE should only be performed on patients with suspected PCa. The National Comprehensive Cancer Network (NCCN) guideline advised that DRE should only be applied to patients with elevated PSA levels. However, the American Urological Association (AUA) guideline did not endorse DRE as a primary screening method because of its questionable accuracy. It recommended that DRE should only be considered as a secondary test (9-11).

Considering the controversies around DRE, and the lack of relevant research on the suspected cancer patients who need a referral for biopsy [Prostate Imaging Reporting and Data System (PI-RADS), PI-RADS ≥3 or PSA ≥4 ng/mL], we conducted a prospective clinical trial (NCT03479359) to evaluate the diagnostic value and the complementary role of DRE in this specific population. We present this article in accordance with the STARD reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-371/rc).

Highlight box

Key findings

- The overall diagnostic accuracy of digital rectal examination (DRE) in patients with suspected prostate cancer (PCa) was 63.45%.
- The true positive rate of DRE for positive tumors was better for peripheral zone tumors compared to those in the central or transition zone.
- A positive DRE was associated with Gleason score ≥7.

What is known and what is new?

- The diagnostic value of DRE in PCa was controversial.
- A prospective trial was designed to investigate the diagnostic performance of DRE under different prostate-specific antigen (PSA) stratifications, and its relationship with tumor location and pathological grade, and also to analyze whether DRE had added value compared to multiparametric magnetic resonance imaging.

What is the implication, and what should change now?

- In clinical practice, DRE is recommended as an alternative auxiliary examination to screen patients with elevated PSA levels and assist doctors in quickly assessing the location and aggressiveness of the tumor, thus contributing to the initial diagnostic process.

Methods

Study design

The clinical and pathological data of patients with positive multiparametric magnetic resonance imaging (mpMRI) (PI-RADS ≥3) or elevated PSA (PSA ≥4 ng/mL) who visited the Department of Urology of Shanghai Changhai Hospital from February 2020 to May 2021 were prospectively and continuously included in our database. These patients were subsequently referred for biopsy.

Before the biopsy, all patients were required to undergo DRE, and the inspection operation was completed by eight trained and experienced urologists [including residents (n=4) and attending physicians (n=4)]. All doctors were required to fill out a form about the DRE results, including if there were any induration, nodularity, or loss of anatomical landmarks of the prostate, and the examiner's comprehensive judgment of whether there were malignant tumors. Doctors were blind to the PSA value and MRI results before the examination. Patients then routinely underwent 12-core or 20-core ultrasound-guided transperineal prostate systemic needle biopsy. Patients with larger prostates may require biopsies of up to 24 cores. Some patients had a targeted biopsy based on mpMRI images. Pathological diagnosis and Gleason score (GS) were provided by professional uropathologists based on biopsy specimens. Tumor location was independently

Table 1 Patient characteristics

Characteristics	All (n=580)	Prostate cancer (n=284)	Negative biopsy (n=296)
Age (years), mean ± SD	65.68±6.85	67.08±6.54	64.34±7.13
BMI (kg/m^2), mean ± SD	24.02±2.80	24.27±2.91	23.78±2.69
PSA (ng/mL), median (IQR)	11.73 (7.78–21.86)	17.05 (9.77–50.47)	9.61 (7.07–13.18)
Men with MRI results, n	100	58	42
DRE results, n			
Positive	266	169	97
Negative	314	115	199

SD, standard deviation; BMI, body mass index; PSA, prostate-specific antigen; IQR, interquartile range; MRI, magnetic resonance imaging; DRE, digital rectal examination.

reviewed and evaluated by experienced urologists based on positive biopsy core areas, DRE, or MRI results. Patients who did not ultimately undergo DRE or biopsy were excluded from the analysis cohort.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Shanghai Changhai Hospital Ethics Committee (No. CH-Urology-DRE-001) and informed consent was taken from all the patients.

Statistical analysis

According to pathological diagnosis and DRE results, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of DRE in diagnosing PCa were calculated. The patients were then further stratified by PSA level into three groups: Group 1: (4≤ PSA <10 ng/mL); Group 2: (10≤ PSA <20 ng/mL); Group 3: (PSA ≥20 ng/mL). The sensitivity, specificity, PPV, and NPV of DRE in each group were calculated. For the patients with confirmed PCa, the two-tailed Student's *t*-test for unpaired data was used to investigate the relationship between DRE and GS. The Pearson Chi-squared test was used to analyze the differences in DRE accuracy between residents and attending physicians and the relationship between tumor location/GS ≥7 PCa and DRE positivity. For the patients with mpMRI results, the efficacy of the combination of DRE and mpMRI in diagnosing PCa was assessed and compared with mpMRI alone to examine whether DRE could assist mpMRI in diagnosing PCa. SPSS22.0 (IBM, Armonk, NY, USA) was used to analyze the data. All P values were two-sided, and a difference of P<0.05 was considered statistically significant.

Results

Patient characteristics

A total of 597 patients were consecutively enrolled in this prospective study. Of these patients, patients who refused to go through DRE (n=14) and patients who did not go through prostate biopsy because of contraindications of anesthesia (for instance, high blood pressure or arrhythmia), thus having no pathological diagnosis (n=3) were excluded to give a final cohort for analysis of 580 patients (Figure S1). *Table 1* lists patient characteristics, encompassing baseline clinical parameters, PSA levels, accessibility of MRI findings, and DRE results.

The value of DRE in diagnosing PCa

Out of the 580 patients, 284 were diagnosed with PCa through pathological confirmation, while 296 exhibited no signs of PCa after undergoing a prostate biopsy. The overall sensitivity, specificity, PPV, and NPV of DRE were determined to be 59.51%, 67.23%, 63.53%, and 63.38%, respectively. The overall accuracy of DRE was found to be 63.45%. We found no significant difference between the residents and attending physicians in terms of diagnostic accuracy (61.99% *vs.* 66.49%, P=0.29).

The patients were further categorized into groups based on their PSA levels. Patients with PSA <4 (n=11) were excluded from this study phase. All remaining patients were divided into three groups based on the level of PSA, the sensitivity, specificity, PPV, and NPV of DRE in diagnosing PCa under different PSA stratifications which are shown in *Table 2*.

Table 2 The diagnostic value of DRE in PSA-stratified patients

PSA level (ng/mL)	No. of men	PCa, n [%]	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
4–<10	225	76 [34]	23.68	74.50	32.14	65.68
10–<20	183	79 [43]	63.29	60.58	54.96	68.48
≥20	161	129 [80]	79.84	53.12	87.29	39.53

DRE, digital rectal examination; PSA, prostate-specific antigen; PCa, prostate cancer; PPV, positive predictive value; NPV, negative predictive value.

Relationship between DRE and PCa anatomical divisions and pathological results

Out of 284 patients with PCa, 229 patients had tumors detected in the peripheral zone, while 55 were found to have tumors only in the central and/or transition zone. Notably, there was a correlation between DRE positivity and peripheral zone PCa (PZ PCa) (P<0.001). Overall, the sensitivity of DRE to recognize PZ PCa was 65.50%, compared with 34.55% to recognize non-PZ PCa.

We compared the GS between the DRE-positive cohort and the DRE-negative cohort. The mean GS for the DRE-positive cohort was 7.92±1.01, whereas that of the DRE-negative cohort was 7.11±0.99 (P<0.001) (Table S1). Furthermore, our analysis revealed a correlation (P<0.001) between the DRE positivity and clinically significant PCa (GS ≥7), with a sensitivity of 65.99% for DRE to recognize GS ≥7 PCa.

Efficacy of mpMRI in diagnosing PCa and the potential of combining DRE and MRI

A hundred patients had mpMRI results, the accuracy, sensitivity, and specificity of mpMRI in diagnosing PCa were 78.00%, 86.21%, and 66.67% respectively in these patients. When patients with either positive MRI results or positive DRE results are considered positive, the accuracy, sensitivity, and specificity were 75.00%, 93.10%, and 50.00%, respectively. When patients with both positive MRI and DRE results are considered positive, the accuracy, sensitivity, and specificity were 59.00%, 37.93%, and 88.10%, respectively. This suggested that the value of DRE combined with MRI in differentiating PCa is limited.

Discussion

Early-stage PCa demonstrates a favorable prognosis, boasting a 5-year survival rate exceeding 99% (12). The EAU suggested that early detection of PCa can reduce PCa-related mortality and lower the risk of being diagnosed and developing advanced or metastatic disease (13). Statistical modeling analysis conducted by the Cancer Intervention and Surveillance Modeling Network of the National Cancer Institute (CISNET) indicated that PCa screening can lead to a 25–32% reduction in PCa-related mortality (14). While PSA detection and DRE form the foundation of PCa screening, their sensitivity, and specificity still need to be improved. Ongoing optimization efforts primarily concentrate on enhancing PSA testing, exploring novel biomarkers derived from body fluids (such as cell-free DNA, circulating tumor cells, and exosomes), leveraging advanced imaging technology, and implementing targeted biopsy techniques (15-17). However, the diagnostic value and role of DRE remain highly controversial, lacking consensus among different guidelines.

DRE was historically the only method for evaluating PCa. This method boasts affordability and simplicity, enabling operators to gain intuitive insights into the size, consistency, and symmetry of the prostate. However, it is crucial to recognize that DRE heavily relies on the operator's subjective judgment and clinical experience (18). Consequently, the existence of this technical threshold gives rise to varying conclusions regarding the diagnostic value of DRE across disparate cohort studies. A meta-analysis by Mistry *et al.* (19) pooled the diagnostic efficacy of PSA and DRE and found that the pooled sensitivity, specificity, and PPV of PSA were 72.1%, 93.2%, and 25.1%, respectively; DRE were 53.2%, 83.6%, and 17.8% respectively. There may be a need to identify ways such as age-specific cut-offs or standardized DRE to increase the efficiency of the screening method. Another meta-analysis evaluated the diagnostic accuracy of DRE for PCa screening in primary care settings and found that the pooled sensitivity, specificity, and PPV of DRE performed by primary care clinicians were 51%, 59%, and 41%, respectively. Therefore, using DRE as a

screening method in primary care is not recommended to avoid unnecessary diagnosis and treatment. On the other hand, the retrospective study by Walsh *et al.* (20) pointed out that DRE is still very important for the early detection of PCa; 35% of patients with normal PSA value have PCa, and the sensitivity of DRE alone is 81%. Referral is still required for those with abnormal DRE even if their PSA is normal. Crawford *et al.* (21) found that the combination of PSA detection with a cut-off value of 4.0 ng/mL and DRE can further improve the diagnostic performance of a single test. Halpern *et al.* (22) retrospectively evaluated the records of 35,530 patients who underwent PCa screening and concluded that men with abnormal DRE and PSA ≥3 ng/mL had an increased risk of clinically significant PCa compared with those with normal DRE (PPV 49% *vs.* 22%). The contradictory perspectives highlight that the advancing medical diagnostic technologies have increasingly constrained the screening value of DRE. The diagnostic efficacy of DRE alone remains unreliable. However, exploring optimization strategies such as patient stratification and combined testing can potentially maximize the value of DRE.

The overall sensitivity, specificity, PPV, and NPV of DRE were 59.51%, 67.23%, 63.53%, and 63.38%, respectively, which showed limited diagnostic value. After stratifying by PSA level, DRE showed different diagnostic efficacy and screening tendencies. The sensitivity and PPV of DRE diagnosis increased with higher PSA levels, while the specificity decreased. This suggested that stratifying PSA further and combining it with DRE did not visually improve the diagnostic efficacy. Only when PSA ≥20 ng/mL, the diagnostic accuracy of DRE was higher than that without stratification (74.53% *vs.* 63.45%), this indicated that DRE might be associated with more aggressive PCa. It is worth noting that in clinical practice, the efficacy requirements of DRE can have different weights under different levels. For example, in the "gray zone" of high false positive rates (4 ng/mL ≤ PSA < 10 ng/mL), we pay more attention to the specificity of screening. At this level, DRE only serves as a reflex test to improve specificity and reduce overdiagnosis in the disease-free population. Although Halpern *et al.* (22) suggested limiting the use of DRE as an auxiliary test to improve specificity in patients with elevated PSA, our study indicated that this effect may be limited to patients with mildly elevated PSA, with significant bias (sensitivity less than 25%), thus providing limited overall screening value.

We found DRE was more likely to detect PZ PCa (65.50%) than tumors from the central zone or transition zone (34.55%) since the peripheral zone was closest to the tectum thus nodularity was easy to palpate by DRE. PCa patients with a positive DRE had a significantly higher GS compared to those with a negative DRE (7.92 *vs.* 7.11). This indicated that DRE was more inclined to detect high-risk PCa patients. In line with our study, a prospective study by Borden *et al.* (23) found that abnormal DRE results were an independent predictor of GS ≥7 PCa (odds ratio =3.39, P=0.001). Therefore, DRE may still hold significant value for diagnosing clinically significant PCa. However, as expected, DRE had no additional diagnostic value on mpMRI findings (24).

Our study has some limitations. First, the study did not include routine DRE patients with PSA <4 ng/mL, and only reflected the diagnostic performance of DRE in patients who underwent needle biopsy. However, the sensitivity of DRE in men with PSA <4 ng/mL might be lower, and whether this group of men needs a DRE examination is also a topic that requires further research and discussion. Second, this study did not fully consider the association between prostate volume and tumor pathology, nor did it analyze the pathologies affecting the recruited patients. Third, DRE is a subjective detection method, and the agreement in interpreting DRE results among different medical institutions and examiners is hard to ensure. Lastly, our study did not track the final GS score of patients undergoing radical prostatectomy, which might have caused an undersampling of clinically significant PCa cases and biased the analysis results. Therefore, we can only interpret the conclusions within the specific research design context.

Conclusions

Overall, although the diagnostic value of DRE alone is limited, it may serve as an adjunctive diagnostic tool for suspected cancer patients, assisting physicians in determining the necessity of biopsy following PSA levels. Additionally, it can provide preliminary information regarding the potential location and pathological grading of PCa, aiding in early prognosis assessment and stratified clinical management of patients. However, some factors that may affect the accuracy and reliability of DRE including operator experience, patient tolerance, prostate size and shape, and the presence of other benign prostate diseases need to be fully considered. The necessity of DRE in normal PSA populations still needs further

exploration.

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-371/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-23-371/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-371/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Shanghai Changhai Hospital Ethics Committee (No. CH-Urology-DRE-001) and informed consent was taken from all the patients.

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