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ORIGINAL RESEARCH

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Clinical study on mpMRI/TRUS software fusion-guided transperineal prostate biopsy

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Abstract

Background: To enhance prostate cancer diagnosis, multiparametric Magnetic Resonance Imaging (mpMRI) combined with Transrectal Ultrasound (TRUS) fusion-guided biopsy has emerged as a promising technique. This study aimed to evaluate its clinical benefits over traditional TRUS-guided biopsy. **Methods**: A retrospective analysis was performed on 83 patients diagnosed between January 2022 and April 2024. Patients were divided into two groups: 41 underwent mpMRI/TRUS fusion-guided biopsy, while 42 had traditional TRUS-guided biopsy. The baseline characteristics of both groups were similar, facilitating a direct comparison of diagnostic efficacy and complication rates. **Results**: The fusion-guided group showed a significantly higher detection rate of clinically significant prostate cancer (21/41 vs. 12/42, $p = 0.035$). It also detected more clinically significant cases (20/41 vs. 11/42, $p = 0.033$). Notably, the fusion group experienced fewer complications, including no instances of hematochezia ($p = 0.003$) or infections ($p = 0.012$), and reported lower postoperative pain levels (Visual Analog Scale score 1.8 ± 0.78 vs. 2.33 ± 1.07, $p = 0.012$). **Conclusions**: The integration of mpMRI with TRUS in fusion-guided biopsy enhances the accuracy of detecting clinically significant prostate cancer, reduces procedural complications, and minimizes patient discomfort. This approach represents a significant advancement in prostate cancer management, improving both diagnostic outcomes and patient safety.

Keywords

Multiparametric magnetic resonance imaging; Transrectal ultrasound; Transperineal prostate biopsy; Prostate cancer

1. Introduction

Prostate cancer is the second most commonly diagnosed cancer in men worldwide, with an estimated 1.4 million new cases and over 375,000 deaths annually, as of 2020 [1]. Its incidence and mortality rates are surpassed only by lung cancer. Despite significant progress in early detection resulting in improved survival rates in developed countries. Prostate cancer remains a major health challenge globally. In developing countries, the lack of widespread screening programs and effective diagnostic tools has resulted in patients being diagnosed at more advanced stages, where treatment options are limited, and survival rates are lower. This highlights the urgent need for more effective and accurate diagnostic methods that can be widely implemented across diverse healthcare settings.

Traditionally, the standard method for diagnosing prostate cancer has been the transrectal ultrasound (TRUS)-guided prostate biopsy [2]. However, it highly depends on the physician's experience and skill, and it has a known false-negative rate [3]. The limitations of this method are primarily evident in its low detection rate of prostate cancer, particularly for lesions located in the anterior zone of the prostate or smaller lesions. Furthermore, due to the inability to precisely locate lesions, multiple biopsy attempts are often required, which not only increases patient discomfort and pain but also raises the risk of infections and other complications [4].

Multiparametric Magnetic Resonance Imaging (mpMRI) has emerged as a valuable imaging tool in recent years diagnosing and managing prostate cancer [5]. Unlike traditional imaging methods, mpMRI combines T2-weighted imaging, diffusion-weighted imaging (DWI), and dynamic contrast-enhanced (DCE) MRI sequences to provide comprehensive insights into prostate anatomy, tumor location, and lesion aggressiveness [6]. The high soft tissue contrast resolution of mpMRI allows it to differentiate between benign and malignant tissue more effectively than TRUS, particularly in challenging areas like the anterior prostate or in patients with prior negative biopsy results. However, mpMRI alone can be costly, and its availability is limited in certain regions or clinical settings, reducing its accessibility for broader populations. To overcome these limitations, the combination of mpMRI with real-time TRUS via software fusion has gained attention as a promising approach for prostate biopsy [7]. The mpMRI/TRUS software

fusion technique integrates the detailed anatomical imaging provided by mpMRI with the real-time guidance of TRUS, allowing for precise lesion targeting during biopsy. This technology merges the high-resolution imaging capabilities of mpMRI with the real-time guidance of TRUS, enabling more precise targeting of lesions during biopsy. This approach notably offers improved accuracy in detecting clinically significant prostate cancer (CsPCa), which is often defined as a Gleason score of $\geq$7 or based on other high-risk features such as elevated prostate-specific antigen (PSA) levels, tumor volume, and pathology characteristics. This distinction is vital, as CsPCa is more likely to progress and require active treatment, whereas lower-risk cases might be managed with active surveillance. This study aims to evaluate the application value of mpMRI/TRUS software fusion-guided transperineal prostate biopsy in diagnosing prostate cancer through clinical trials. By comparing it with traditional TRUS-guided prostate biopsy techniques, this study aims to comprehensively reveal the potential advantages of mpMRI/TRUS software fusion technology in enhancing prostate cancer detection rates, reducing complication rates, and improving patient experience [5].

2. Research objectives and hypotheses

2.1 Primary objective

The primary objective of this study is to evaluate the clinical value of multiparametric Magnetic Resonance Imaging (mpMRI) combined with Transrectal Ultrasound (TRUS) software fusion-guided transperineal prostate biopsies in diagnosing prostate cancer. This innovative fusion technology seeks to compare its diagnostic accuracy with traditional TRUS-guided prostate biopsy techniques and to assess its effectiveness in reducing procedure-related complications.

2.2 Specific objectives

To compare prostate cancer detection rates between mpMRI/TRUS software fusion-guided biopsy and traditional TRUS-guided prostate biopsy techniques.

To assess the incidence of biopsy-related complications (such as hematuria, hematochezia, infections and pain) between the two methods.

To evaluate whether the mpMRI/TRUS fusion technique reduces patient discomfort.

2.3 Hypotheses

Hypothesis 1: The use of mpMRI/TRUS software fusion technology for transperineal prostate biopsies will significantly increase the detection rate of prostate cancer, particularly in identifying clinically significant cancers, offering a distinct advantage over traditional TRUS-guided biopsy techniques.

Hypothesis 2: The enhanced imaging and targeting capabilities provided by mpMRI/TRUS fusion, leading to more precise targeting during biopsies, can reduce the incidence of biopsy-related complications such as infections, bleeding and postoperative pain, resulting in better overall patient tolerance.

These hypotheses are based on the premise that combining mpMRI's detailed anatomical visualization capabilities with TRUS's real-time imaging will offer a more effective and patient-friendly approach to diagnosing prostate cancer.

3. Materials and methods

3.1 Study design

This study employed a retrospective analysis design, spanning from January 2022 to April 2024, to assess the clinical application value of mpMRI/TRUS software fusion-guided transperineal prostate biopsies in diagnosing prostate cancer. The research was carried out at Haicang Hospital in Xiamen City, approved by the hospital's ethics committee, and all participating patients provided informed consent before enrollment.

3.2 Study participants

The study included 83 patients suspected of having prostate cancersuspected prostate cancer patients. Forty-one patients underwent mpMRI/TRUS software fusion-guided transperineal prostate biopsies (fusion group), while 42 patients underwent traditional TRUS-guided prostate biopsies (control group). Preoperatively, both groups received digital rectal examinations, prostate MRI scans (with and without contrast), total PSA (tPSA) tests, and prostate ultrasonography.

Inclusion criteria: Abnormal nodules detected by digital rectal examination; suspicious lesions indicated by mpMRI or TRUS; PSA $>$10 ng/dL or PSA values between 4–10 ng/dL with abnormal free/total PSA (f/tPSA) ratios or PSA density (PSAD).

Exclusion criteria: Preoperative uncontrolled infections such as urinary tract infections or acute prostatitis; failure to meet the safety interval for discontinuing anticoagulant or antiplatelet medications; coagulation disorders; non-initial prostate biopsy; patients with hemorrhoids or perianal diseases.

3.3 Data collection tools and surgical methods

All patients underwent enhanced prostate mpMRI scans using high-resolution MRI equipment, to capture T2-weighted imaging (T2WI), diffusion-weighted imaging (DWI), and apparent diffusion coefficient (ADC) sequences, to ensuring clear visualization of the prostate structure.

TRUS examinations were performed with the latest Carbon fusion ultrasound equipment, providing accurate and flexible real-time imaging.

For mpMRI/TRUS software fusion, the same Carbon fusion ultrasound equipment was used to real-time merge mpMRI images with TRUS images in real time.

Surgical method:

Fusion group: mpMRI/TRUS software fusion technology guided the transperineal prostate biopsy.

Specific steps are as follows:

(1) Patients received routine prophylactic anti-infection treatment with levofloxacin or third-generation cephalosporins a day before surgery. Enhanced preoperative prostate MRI

scans were conducted to determine the location and extent of suspicious lesions in the prostate. T2WI, DWI and ADC multi-sequence images were imported into the Carbon fusion ultrasound machine.

(2) After successful anesthesia, the patient was placed in the lithotomy position, with the scrotum elevated, routine disinfection and draping were performed, and an F14 catheter was inserted.

(3) The Carbon fusion ultrasound machine was started, and the mpMRI data were imported, the frame showing where the tip of the prostate was just visible and the base almost disappearing was selected for mpMRI image reconstruction. T2WI/DWI/ADC were used to mark suspicious lesions. Ultrasound coupling gel was applied to the crystal surface of the transrectal dual-plane ultrasound probe, which was then inserted into the rectum using a sterile cover. The prostate's ultrasonic image was observed and dimensions measured to calculate prostate volume. Data collection began from the tip of the prostate, with the ultrasound probe slowly advancing into the rectum until the sagittal contour of the prostate was fully scanned. Upon clicking "merge", the software system automatically completed the mpMRI/TRUS fusion of prostate images and precisely located both the targeted and systematic biopsy sites.

(4) With the biopsy guide in position, the corresponding fusion image showed both systematic and targeted biopsy sites, with needle guidance enabled for direct access to the biopsy pathway. Standard systematic (12 needles) + targeted (X needles) biopsies were conducted, starting with targeted and then systematic biopsies.

(5) Biopsy specimens were removed from the biopsy gun and transferred into 10% formalin containers.

(6) After the biopsy, the perineal area was checked for hematoma, and gauze compression bandaging was applied to the biopsy site and monitored for urethral bleeding and changes in urine color.

Control group: Traditional transrectal ultrasound-guided prostate biopsy was performed, usually including systematic biopsies (at least 12 needles).

(1) Patients were administered standard prophylactic antibiotics with levofloxacin or third-generation cephalosporins a day before the surgery, and an F14 catheter was placed after successful anesthesia. The patient was positioned in the left lateral decubitus position facing the surgeon with exposed buttocks, and standard sterilization and draping.

(2) A rectal tube was placed, and the rectal wall was cleansed with a povidone-iodine enema, gently dilating the anus with fingers.

(3) Ultrasound coupling gel was applied to the crystal surface of the transrectal ultrasound probe, which was then attached to a biopsy guide and gradually inserted into the rectum to aim the ultrasound beam at the prostate.

(4) By adjusting the ultrasound probe position, altering the coronal and sagittal prostate ultrasound views, measuring prostate dimensions and calculating prostate volume. Detected abnormal ultrasound signals or suspicious nodules were documented.

(5) Based on the observed prostate ultrasound images, systematic prostate biopsy needle count and layouts were determined.

(6) Generally, an 18G biopsy needle was used, and following each biopsy, the specimen was placed in a 10% formalin container.

(7) After the biopsy, the ultrasound probe was withdrawn, and the biopsy site was cleansed with povidone-iodine gauze. If a clear bleeding point was observed in the rectal wall, compression was applied for the hemostasis. Upon confirming the absence of active bleeding in the rectal wall, povidone-iodine gauze was inserted and left in place for 4–6 hours before removal to assess for significant bleeding.

3.4 Statistical analysis methods

Statistical analyses were conducted using SPSS version 18.0 (Version 18.0, SPSS Inc., Chicago, IL, USA). Categorical data were expressed as percentages and frequencies, and comparisons between groups were conducted using the Chi-square test; quantitative data was reported as means ± standard deviation (SD), and group comparisons employed independent *t*-tests. A *p*-value of less than 0.05 was considered statistically significant.

4. Results

4.1 Baseline characteristics of the study subjects

This study enrolled 83 suspected prostate cancer patients, with 41 patients undergoing the mpMRI/TRUS software fusion technology (fusion group) and 42 receiving standard TRUS-guided biopsies (control group). The baseline characteristics in both cohorts including age, prostate volume, PSA levels, and PI-RADS scores (Prostate Imaging Reporting and Data System scores) are summarized in Table 1. There were no statistically significant differences between the groups, indicating comparable baseline characteristics (Table 1).

The prostate cancer detection rate is a key indicator for evaluating the effectiveness of biopsy techniques. In this study, the prostate cancer detection rate in the fusion group was significantly higher than that in the control group, particularly in terms of the detection rate of clinically significant prostate cancer (CsPCa), as shown in Table 2.

CsPCa is mainly defined by the Gleason score and the extent of cancer infiltration. Specifically, CsPCa refers to tumors with a Gleason score of $\geq$7 or those that have extracapsular spread.

Regarding complications, the fusion group showed markedly reduced rates of postoperative bleeding (hematochezia) and infections compared to the control group, suggesting that the mpMRI/TRUS fusion may minimize tissue damage and related complications due to more precise targeting (Table 3, Fig. 1).

Postoperative VAS pain scores indicated that the fusion group reported an average pain score of 1.8 ± 0.78 versus 2.33 ± 1.07 in the control group, indicating reduced postoperative pain in the fusion group ($p = 0.012$). The difference between the groups was statistically significant, indicating improved postoperative comfort in the fusion group, enhancing overall patient tolerance.

TABLE 1. Baseline characteristics of all included patients.

Characteristic	Fusion Group (n = 41)	Control Group (n = 42)	*p*-value
Age (yr)	71.60 ± 7.70	69.74 ± 7.68	0.271
Prostate Volume (mL)	62.67 ± 29.95	62.81 ± 27.05	0.982
Preoperative PSA (ng/dL)	109.55 ± 228.85	77.28 ± 219.33	0.514
PI-RADS Score	3.46 ± 0.745	3.48 ± 0.634	0.933

PSA: prostate-specific antigen; PI-RADS: Prostate Imaging Reporting and Data System scores.

TABLE 2. Detection rates of the two methods.

Metric	Fusion Group (n = 41)	Control Group (n = 42)	*p*-value
Prostate Cancer Detection Rate (%)	51.22 (21/41)	28.57 (12/42)	0.035
CsPCa Detection Rate (%)	48.78 (20/41)	26.19 (11/42)	0.033

CsPCa: clinically significant prostate cancer.

TABLE 3. Postoperative complications of the two methods.

Complication	Fusion Group (n = 41)	Control Group (n = 42)	*p*-value
Hematochezia (cases)	0	8	0.003
Hematuria (cases)	4	4	0.971
Infection (cases)	0	6	0.012
Urinary retention (cases)	3	6	0.307

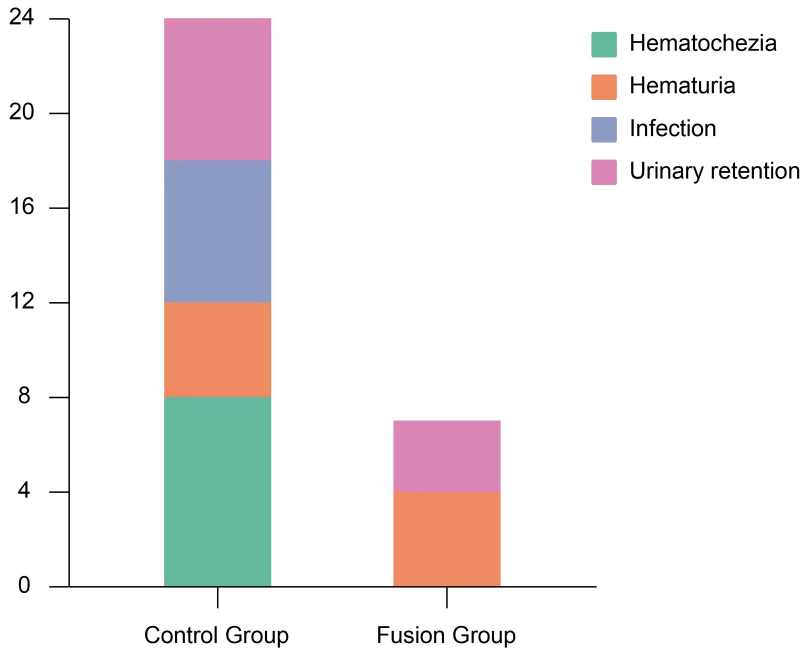

FIGURE 1. Stacked bar chart illustrating the distribution of postoperative complications in patients of the control group and fusion group.

4.2 Analysis of statistical significance

The statistical analysis results support the research hypotheses, demonstrating that mpMRI/TRUS software fusion-guided transperineal prostate biopsy is more effective in enhancing prostate cancer detection rates, minimizing complications, and improving the postoperative recovery experience for patients compared to traditional TRUS-guided prostate biopsy techniques. These findings underscore the clinical value and potential of fusion technology prostate cancer diagnosis.

5. Discussion

5.1 Analysis of the advantages of mpMRI/TRUS fusion technology

The results of this study indicate that mpMRI/TRUS software fusion-guided transperineal prostate biopsy significantly outperforms traditional transrectal ultrasound-guided prostate biopsy in improving prostate cancer detection rates and reducing biopsy-related complications. The key advantage of the fusion technology is its capability to combine the high-resolution imaging features of mpMRI with the real-time guidance provided by TRUS, providing precise lesion localization and dynamic biopsy guidance. This technology not only improves the positive detection rate of prostate cancer biopsies but also minimizes tissue damage associated with less accurate methods, markedly lowering the incidence of biopsy-related complications such as bleeding and infection. Furthermore, the biopsy precision greatly reduces postoperative pain and discomfort, enhancing the overall patient experience. Notably, this integration not only enhances visualization and detection of suspicious lesions but also provides a foundation for precise targeting, especially in challenging prostate zoneswith TRUS alone.

Moreover, Gleason upgrading is a well-known phenomenon in prostate cancer diagnostics, referring to the finding that Gleason scores assigned based on biopsy samples may be lower than those assigned after radical prostatectomy. This discrepancy is largely due to the limitations of sampling in biopsy techniques. Research indicates that mpMRI/TRUS fusion-guided biopsies decrease the rate of Gleason upgrading by more accurately targeting suspicious lesions. This allows for a more accurate representative assessment of the tumor's histological grade, thus enhancing diagnosis and treatment planning.

5.2 Comparison with existing research results

Comparing the results of this study with existing literature, the prostate cancer detection rate with mpMRI/TRUS fusion technology is significantly higher than the average detection rates reported globally for traditional TRUS-guided biopsies, typically ranging between 20 and 30% [8]. For instance, a large-sample international study reported a detection rate of approximately 25% with traditional methods [9]. In contrast, the detection rate in the fusion group of this study was 51.22%, demonstrating a substantial improvement. This improvement was due to the combination of mpMRI's detailed anatomical imaging and the real-time guidance of TRUS, leading to improved diagnostic accuracy and greater flexibility during the biopsy procedure. Moreover, this study supports findings from other research, further validating the superiority of mpMRI/TRUS fusion in detecting clinically significant prostate cancer (CsPCa). This is vital for improving patient outcomes and for developing personalized treatment strategies. Furthermore, the enhanced ability to visualize and accurately target lesions helps reduce unnecessary biopsies and detect cancers that could have been missed by traditional methods.

5.3 Potential clinical impacts and application prospects of the technology

The clinical application prospects of mpMRI/TRUS fusion technology are vast, significantly improving the early diagnosis rate of prostate cancer and facilitating the formulation of more precise treatment plans for patients. In terms of treatment planning, the technology can accurately define tumor location and extent, offering accurate targeting information for radiation therapy or surgery, thereby maximizing normal tissue preservation and minimizing the treatment-related side effects. As personalized medicine advances, mpMRI/TRUS fusion technology could also play a pivotal role in active surveillance, focal therapy, and long-term treatment monitoring. Its potential to reduce the need for repeat biopsies is particularly valuable, as it reduces patient burden while maintaining diagnostic accuracy. Additionally, by detecting clinically significant prostate cancers earlier, the technology could contribute to better patient management, prognosis evaluation, and improved long-term outcomes.

5.4 Challenges faced and solutions

Despite the numerous benefits of mpMRI/TRUS software fusion technology, it may still face some challenges in practical implementation:

Issues related to image fusion accuracy: Due to factors like patient positioning and bladder filling levels, misalignments may occur in the fusion of mpMRI and TRUS images. Potential solutions improving optimizing image registration algorithms to improve fusion accuracy and real-time monitoring and adjustment during the biopsy process.

Operational technical requirements: This technology demands high technical proficiency from operators, who must have substantial experience in interpreting mpMRI and performing ultrasound operations. Thus, improving training and technical guidance for doctors is crucial.

Challenges related to equipment cost: The equipment and software costs for mpMRI/TRUS software fusion technology are relatively high, which may hinder its widespread adoption in resource-limited areas. Reducing costs and enhancing equipment accessibility are directions that need to be pursued in the future.

5.5 Research limitations and future directions

Despite the significant clinical value of the results, this study has some limitations that need to be addressed. Firstly, as a retrospective study design was used, unavoidable biases such as selection bias and information bias could influence the generalizability of the results. Secondly, the relatively small sample size and the study being limited to a single center may restrict the generalizability of the results. Future studies should consider conducting large-scale, prospective, multicenter research to provide broader evidence support. Additionally, the effectiveness of this technology in diverse populations (such as different races, and different age groups) should be explored, along with long-term monitoring to evaluat the long-term impact of the technology on patient survival and quality

of life.

6. Conclusions

6.1 Summary of research findings

This study, by comparing mpMRI/TRUS software fusion technology with traditional transrectal ultrasound-guided prostate biopsies, demonstrated the significant advantages of fusion technology in diagnosing prostate cancer. The results demonstrate that prostate biopsies guided by mpMRI/TRUS fusion have a significantly improved detection rate of prostate cancer compared to traditional methods, especially for detecting clinically significant prostate cancer (CsPCa). Additionally, this technology also is effective in reducing complications such as surgery-related hematochezia, infections and postoperative pain, thereby improving the treatment experience and postoperative comfort for patients.

6.2 Recommendations for clinical practice

Given the multiple advantages of mpMRI/TRUS software fusion technology in the diagnosis and treatment of prostate cancer, we recommend its application in appropriate clinical settings, particularly in complex cases where traditional diagnostic methods are insufficient. This technology provides more precise lesion localization and risk assessment, which can aid physicians develop more personalized treatment plans and optimize treatment outcomes. Furthermore, considering its potential to reduce complications, mpMRI/TRUS fusion technology can be an important tool to improve the quality of prostate cancer management and patient safety.

Additionally, future research should investigate the long-term effects of this technology, including its impact on patient survival rates and quality of life, as well as its applicability in different populations, to further refine and optimize the clinical application of mpMRI/TRUS fusion technology.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

CY and YJH—designed this study and put it into practice. CY, YJH, YBW, JPW, MHR, CL and YCW—supervised the data collection, analyzed and interpreted the data. CY, YJH and YBW—prepared the manuscript for publication and reviewed the draft. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study has obtained ethical approval from the Medical Ethics Committee of Xiamen Haicang Hospital (Approval Number: LW-2024032), and informed consent has been obtained from all patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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