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TRANSPERINEAL MRI–ULTRASOUND FUSION-GUIDED PROSTATE BIOPSY USING THE KOELIS TRINITY SYSTEM: DIAGNOSTIC OUTCOMES AND INITIAL EXPERIENCE IN A SIX-PATIENT CASE SERIES

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ABSTRACT

Background: Transperineal magnetic resonance imaging–ultrasound (MRI–US) fusion-guided prostate biopsy has emerged as an important diagnostic approach for patients with suspected prostate cancer. The technique enables targeted sampling of suspicious lesions identified on multiparametric MRI (mpMRI), while the transperineal route offers favorable access to anterior prostatic regions and a reduced risk of infectious complications.

Objective: To describe the initial diagnostic outcomes and procedure-related complications of transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity system in a six-patient case series.

Materials and Methods: Six patients with suspicious lesions on prostate mpMRI underwent transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity platform under general anesthesia. Clinical, radiological, and histopathological data were analyzed descriptively. The principal outcome was histologically confirmed prostate cancer. Secondary outcomes included the distribution of biopsy findings according to PI-RADS classification and reported procedural complications.

Results: The mean patient age was 64.8 ± 7.3 years, with a mean PSA level of 11.05 ± 4.43 ng/mL and a mean prostate volume of 75.2 ± 33.0 mL. One patient (16.7%) had a PI-RADS 3 lesion, two (33.3%) had PI-RADS 4 lesions, and three (50.0%) had PI-RADS 5 lesions. Prostatic adenocarcinoma was detected in two patients (33.3%), both classified as International Society of Urological Pathology (ISUP) grade group 1. Four patients (66.7%) had benign histopathological

findings consistent with benign prostatic hyperplasia. No clinically significant prostate cancer (ISUP grade group ≥2) was identified. Two of the three PI-RADS 5 lesions yielded benign histopathological findings. Postprocedural hematuria was reported in one patient, while four patients had no reported complications. Complication information was unavailable for one patient.

Conclusion: This preliminary case series describes the clinical application of transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity system. The findings highlight radiological–histopathological discordance in some highly suspicious lesions and the importance of clinical follow-up after benign targeted biopsy results. Larger prospective studies with standardized biopsy protocols and longitudinal follow-up are required to assess diagnostic performance and safety.

Keywords: Prostate cancer; Transperineal biopsy; MRI–ultrasound fusion; KOELIS Trinity; PI-RADS; Targeted prostate biopsy; Case series**.**

1 INTRODUCTION

Prostate cancer is a major health concern in men worldwide. Early and accurate diagnosis remains essential for distinguishing clinically significant disease requiring treatment from low-grade tumors that may be suitable for surveillance.

Historically, prostate cancer diagnosis has relied on systematic transrectal ultrasound-guided biopsy. However, conventional systematic sampling may fail to identify clinically significant tumors, particularly those located in anterior or apical regions of the prostate. It may also detect low-grade tumors that are unlikely to cause clinically relevant harm.

The introduction of multiparametric magnetic resonance imaging (mpMRI) has substantially modified the diagnostic pathway for suspected prostate cancer. The Prostate Imaging Reporting and Data System (PI-RADS) provides a standardized framework for evaluating suspicious prostatic lesions and estimating the likelihood of clinically significant malignancy [1].

MRI-targeted prostate biopsy has demonstrated important advantages over conventional systematic biopsy in appropriately selected patients. In the PRECISION randomized trial, Kasivisvanathan et al. reported improved detection of clinically significant prostate cancer using an MRI-based diagnostic pathway compared with standard transrectal ultrasound-guided biopsy [2].

MRI–ultrasound fusion technology enables the integration of preoperative MRI findings with intraoperative ultrasound imaging, allowing suspicious lesions to be localized and sampled under image guidance.

The KOELIS Trinity platform is a three-dimensional ultrasound-based fusion system designed to facilitate MRI-targeted prostate biopsy through image registration and lesion localization.

The transperineal approach has gained increasing attention because of its favorable infectious safety profile and its ability to access different anatomical regions of the prostate. The PREVENT randomized trial demonstrated that transperineal biopsy without antibiotic prophylaxis was associated with very low infectious complication rates, while maintaining comparable cancer detection outcomes to transrectal biopsy with targeted antibiotic prophylaxis [3].

Nevertheless, discrepancies between suspicious MRI findings and benign histopathological results remain an important diagnostic challenge. These discrepancies may reflect benign conditions mimicking malignancy on MRI, limitations in lesion targeting, or sampling errors.

We report our initial experience with transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity system in six patients, focusing on diagnostic outcomes, MRI–histopathology relationships, and procedure-related complications.

2 MATERIALS AND METHODS

2.1 Study Design and Patient Population

This descriptive case series included six patients who underwent transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity system for the evaluation of suspected prostate cancer.

The patients had undergone prostate mpMRI demonstrating suspicious or indeterminate lesions classified as PI-RADS categories 3, 4, or 5.

The study describes the clinical characteristics, radiological findings, histopathological results, and reported complications of these six patients.

The study period, institution, patient selection method, and prospective or retrospective nature of data collection remain to be specified.

2.2 Clinical and Radiological Assessment

- Clinical evaluation included serum prostate-specific antigen (PSA) measurement and prostate volume assessment.
- PSA density was calculated by dividing serum PSA concentration (ng/mL) by prostate volume (mL).
- Prostate mpMRI was performed before biopsy. Suspicious lesions were characterized according to their PI-RADS classification, anatomical location, and size when available.
- Lesion localization was recorded according to the peripheral or transition zone and its anatomical position within the prostate.

2.3 Transperineal MRI–Ultrasound Fusion-Guided Biopsy Technique

- All procedures were performed under general anesthesia using the KOELIS Trinity MRI–US fusion platform (KOELIS, France).
- The technique involved the use of preprocedural prostate MRI and intraoperative three-dimensional transrectal ultrasound imaging for image registration and localization of suspicious lesions.
- MRI-identified targets were sampled using a transperineal biopsy approach under fusion guidance.

The number of targeted biopsy cores, use of systematic or perilesional sampling, needle specifications, patient positioning, antimicrobial prophylaxis, and operator experience were not available in the current dataset and require confirmation before publication.

2.4 Histopathological Assessment

- Biopsy specimens underwent histopathological evaluation.
- Malignant lesions were classified according to the Gleason grading system and the International Society of Urological Pathology (ISUP) grade groups.
- Clinically significant prostate cancer was defined as ISUP grade group ≥2.
- Benign biopsy findings were recorded as reported in the histopathological results.

2.5 Outcome Measures

The primary outcome was the proportion of patients with histologically confirmed prostate adenocarcinoma.

Secondary outcomes included:

- Distribution of histopathological findings according to PI-RADS classification.
- Detection of clinically significant prostate cancer.
- Description of benign histopathological findings in suspicious MRI lesions.
- Reported procedure-related complications.

2.6 Statistical Analysis

Given the small sample size, descriptive statistics were used.

Continuous variables were summarized using means, standard deviations, medians, and ranges, as appropriate. Categorical variables were expressed as absolute numbers and percentages.

No inferential statistical testing was performed.

3 RESULTS

3.1 Baseline Patient Characteristics

Six patients underwent transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity system under general anesthesia.

- The mean age was 64.8 ± 7.3 years (range: 53–75 years), and the median age was 65.5 years.
- The mean PSA level was 11.05 ± 4.43 ng/mL (range: 7–18.36 ng/mL), with a median value of 10.0 ng/mL.
- The mean prostate volume was 75.2 ± 33.0 mL (range: 22–123 mL), with a median volume of 74 mL.
- The median PSA density was 0.157 ng/mL/mL.

3.2 MRI Findings

According to PI-RADS classification, one patient (16.7%) presented with a PI-RADS 3 lesion, two patients (33.3%) with PI-RADS 4 lesions, and three patients (50.0%) with PI-RADS 5 lesions.

Three lesions were explicitly located in anterior prostatic regions, while the remaining lesions were located in the posterior basal region, basal peripheral zone, or transition zone without further sublocalization.

Lesion dimensions were available for three patients.

3.3 Histopathological Findings

Prostatic adenocarcinoma was detected in two of the six patients (33.3%). Both tumors were classified as ISUP grade group 1, corresponding to Gleason score 3 + 3 = 6.

The remaining four patients (66.7%) had benign histopathological findings reported as benign prostatic hyperplasia.

No clinically significant prostate cancer, defined as ISUP grade group ≥2, was identified in the available biopsy results.

Cancer was identified in one of the two PI-RADS 4 cases and one of the three PI-RADS 5 cases. The patient with a PI-RADS 3 lesion had benign histopathological findings.

3.4 Individual Case Presentations

3.4.1 Case 1

A 68-year-old man presented with a PSA level of 12 ng/mL and a prostate volume of 22 mL, corresponding to a PSA density of 0.545 ng/mL/mL. MRI identified a PI-RADS 4 lesion in the left anterior peripheral zone. Transperineal MRI–US fusion-guided biopsy revealed prostatic adenocarcinoma, ISUP grade group 1. Complication data were not available.

3.4.2 Case 2

A 53-year-old man had a PSA level of 13.41 ng/mL and a prostate volume of 68 mL, corresponding to a PSA density of 0.197 ng/mL/mL. MRI demonstrated a PI-RADS 5 lesion measuring 16 × 13 mm in the left posterior region of the prostatic base. Fusion-guided biopsy revealed benign prostatic hyperplasia. No procedure-related complications were reported.

3.4.3 Case 3

A 64-year-old man had a PSA level of 7 ng/mL and a prostate volume of 80 mL, corresponding to a PSA density of 0.088 ng/mL/mL. MRI demonstrated a PI-RADS 5 lesion in the right anterior transition zone. Histopathological examination revealed prostatic adenocarcinoma, ISUP grade group 1. Postprocedural hematuria was reported, without additional details regarding severity or management.

3.4.4 Case 4

A 67-year-old man presented with a PSA level of 7.5 ng/mL and marked prostatic enlargement, with a volume of 123 mL and a PSA density of 0.061 ng/mL/mL. MRI identified a 9-mm PI-RADS 4 lesion in the left anterior transition zone. Histopathological examination demonstrated benign prostatic hyperplasia. No procedure-related complications were reported.

3.4.5 Case 5

A 62-year-old man had a PSA level of 8 ng/mL and a prostate volume of 68 mL, corresponding to a PSA density of 0.118 ng/mL/mL. MRI demonstrated a PI-RADS 5 lesion measuring 16 × 13 mm in the left peripheral zone at the prostatic base. Targeted biopsy revealed benign prostatic hyperplasia. No complications were reported.

3.4.6 Case 6

A 75-year-old man presented with a PSA level of 18.36 ng/mL and a prostate volume of 90 mL, corresponding to a PSA density of 0.204 ng/mL/mL. MRI identified a PI-RADS 3 lesion in the left transition zone. Fusion-guided biopsy demonstrated benign prostatic hyperplasia. No procedure-related complications were reported.

Table 1: Baseline clinical characteristics of the six patients

Variable	Value
Number of patients	6
Age, mean ± SD, years	64.8 ± 7.3
Age, median (range), years	65.5 (53–75)
PSA, mean ± SD, ng/mL	11.05 ± 4.43
PSA, median (range), ng/mL	10.0 (7–18.36)
Prostate volume, mean ± SD, mL	75.2 ± 33.0
Prostate volume, median (range), mL	74 (22–123)
PSA density, median, ng/mL/mL	0.157
General anesthesia, n (%)	6 (100.0)
KOELIS Trinity platform, n (%)	6 (100.0)

SD, standard deviation; PSA, prostate-specific antigen.

Table 2: Distribution of MRI findings according to PI-RADS category

PI-RADS category	Patients, n	Patients, %	Cancer detected, n (%)	Benign histopathology, n (%)
PI-RADS 3	1	16.7	0 (0.0)	1 (100.0)
PI-RADS 4	2	33.3	1 (50.0)	1 (50.0)
PI-RADS 5	3	50.0	1 (33.3)	2 (66.7)
Total	6	100.0	2 (33.3)	4 (66.7)

PI-RADS, Prostate Imaging Reporting and Data System.

Table 3: Individual patient characteristics and biopsy outcomes

Case	Age (years)	PSA (ng/mL)	Prostate volume (mL)	PSA density (ng/mL/mL)	PI-RADS	Lesion location	Lesion size	Histopathology	ISUP grade group	Complications
1	68	12.00	22	0.545	4	Left anterior peripheral zone	Not available	Adenocarcinoma	1	Not available
2	53	13.41	68	0.197	5	Left posterior prostatic base	16 × 13 mm	Benign prostatic hyperplasia	Not applicable	None reported

3	64	7.00	80	0.088	5	Right anterior transition zone	Not available	Adenocarcinoma	1	Hematuria
4	67	7.50	123	0.061	4	Left anterior transition zone	9 mm	Benign prostatic hyperplasia	Not applicable	None reported
5	62	8.00	68	0.118	5	Left basal peripheral zone	16 × 13 mm	Benign prostatic hyperplasia	Not applicable	None reported
6	75	18.36	90	0.204	3	Left transition zone	Not available	Benign prostatic hyperplasia	Not applicable	None reported

PSA, prostate-specific antigen; PI-RADS, Prostate Imaging Reporting and Data System; ISUP, International Society of Urological Pathology.

Table 4: Histopathological and complication outcomes

Outcome	Patients, n	Patients, %
Prostatic adenocarcinoma	2	33.3
ISUP grade group 1	2	33.3
ISUP grade group ≥2	0	0.0
Benign prostatic hyperplasia	4	66.7
Postprocedural hematuria	1	16.7
No reported complications	4	66.7
Complication data unavailable	1	16.7

ISUP, International Society of Urological Pathology.

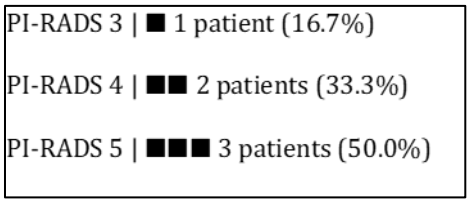


Figure 1: Distribution of patients according to PI-RADS category

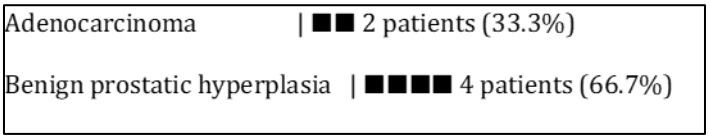


Figure 2: Histopathological outcomes

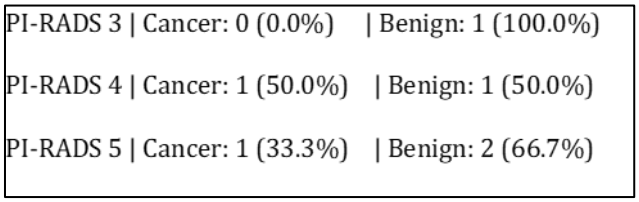


Figure 3: Relationship between PI-RADS category and biopsy outcome

3.5 Procedure-Related Complications

- Postprocedural hematuria was reported in one patient.
- Four patients had no reported complications, while complication data were unavailable for one patient.
- No additional complications were documented in the available records.
- Because complication documentation was incomplete, these findings should not be interpreted as a comprehensive estimate of procedural safety.

4 DISCUSSION

The present case series describes the initial clinical experience with transperineal MRI–US fusion-guided prostate biopsy using the KOELIS Trinity system in six patients with suspicious or indeterminate lesions on prostate mpMRI.

The main findings were a 33.3% proportion of patients with biopsy-confirmed prostate adenocarcinoma, the absence of ISUP grade group ≥2 cancer in the available specimens, and the occurrence of benign histopathological findings in several MRI-suspicious lesions.

4.1 Diagnostic Role of MRI–Ultrasound Fusion-Guided Biopsy

MRI-targeted prostate biopsy represents an important development in the diagnostic evaluation of suspected prostate cancer.

The PRECISION trial demonstrated that an MRI-based diagnostic pathway improved the detection of clinically significant prostate cancer compared with conventional systematic transrectal biopsy in biopsy-naïve patients [2].

MRI–US fusion systems enable suspicious lesions to be targeted through the integration of MRI findings and ultrasound guidance.

In the present series, prostate adenocarcinoma was identified in two patients, both with ISUP grade group 1 disease.

However, because no control group was included and systematic biopsy findings were not separately documented, the present study cannot establish the superiority of fusion-guided biopsy over conventional biopsy techniques.

4.2 Radiological–Histopathological Discordance

An important observation was the presence of benign histopathological findings in two of the three patients with PI-RADS 5 lesions.

PI-RADS 5 lesions are generally associated with a high likelihood of clinically significant prostate cancer. Nevertheless, benign prostatic conditions, including stromal hyperplasia and inflammatory changes, may produce suspicious MRI appearances.

In addition, negative biopsy results may occur because of targeting inaccuracies, sampling limitations, or intralesional heterogeneity.

The European Association of Urology guidelines emphasize the integration of MRI findings, PSA density, clinical risk factors, and biopsy results when evaluating patients with suspected prostate cancer [4].

In the present series, the benign results obtained in patients with PI-RADS 5 lesions should therefore be interpreted cautiously.

Without longitudinal follow-up, repeat MRI, or repeat biopsy data, it is not possible to determine whether these findings represent benign MRI mimics or false-negative biopsy results.

4.3 Relationship Between PSA Density and Histopathology

PSA density may provide complementary information when interpreting prostate MRI findings.

In this series, PSA density varied considerably between patients, ranging from 0.061 to 0.545 ng/mL/mL.

Interestingly, one patient with a PI-RADS 5 lesion and a relatively low PSA density of 0.088 ng/mL/mL had biopsy-confirmed ISUP grade group 1 prostate adenocarcinoma.

Conversely, another patient with a PI-RADS 3 lesion and a PSA density of 0.204 ng/mL/mL had benign histopathological findings.

These observations illustrate the limitations of interpreting PSA density in isolation. PSA density should be considered alongside MRI findings, clinical characteristics, and histopathological results.

4.4 Advantages of the Transperineal Approach

The transperineal biopsy approach has become increasingly important because of its favorable infectious safety profile.

In the PREVENT randomized trial, Hu et al. compared transperineal biopsy without antibiotic prophylaxis with transrectal biopsy using targeted antibiotic prophylaxis. The study reported no infectious complications in the transperineal group and comparable clinically significant cancer detection between the two approaches [3].

The transperineal route also provides anatomical access to anterior and apical regions of the prostate, which may be less reliably sampled by conventional transrectal systematic biopsy.

In the present series, three patients had lesions explicitly located in anterior prostatic regions, including the anterior peripheral and anterior transition zones.

The use of the KOELIS Trinity platform enabled these lesions to be targeted under MRI–US fusion guidance.

However, the present series does not provide comparative data on targeting accuracy or the relative performance of the transperineal and transrectal approaches.

4.5 Procedure-Related Safety

Transperineal prostate biopsy is generally associated with a low risk of infectious complications, although noninfectious adverse events, including hematuria, urinary retention, and perineal discomfort, may occur.

In our series, one patient developed postprocedural hematuria, while four patients had no reported complications.

The severity, duration, and management of hematuria were not documented.

Although these findings are compatible with the established safety profile of transperineal biopsy, the small sample size and incomplete complication documentation prevent definitive conclusions regarding procedural safety.

4.6 Clinical Implications

The present findings highlight several clinically relevant considerations.

First, MRI–US fusion-guided transperineal biopsy can be applied to suspicious lesions in different anatomical regions of the prostate, including anterior locations.

Second, a benign histopathological result in a highly suspicious MRI lesion should not automatically be considered definitive exclusion of prostate cancer.

Third, PSA density and PI-RADS classification provide complementary information, but neither parameter should be interpreted independently of the overall clinical context.

Finally, systematic documentation of biopsy core distribution, histopathological findings, complications, and follow-up is essential for evaluating the clinical performance of image-fusion biopsy systems.

4.7 Study Limitations

The present study has several important limitations.

- The first limitation is the very small sample size of six patients, which substantially restricts the generalizability of the findings.
- Second, the absence of a comparator group prevents evaluation of the relative diagnostic performance of transperineal fusion-guided biopsy versus conventional systematic or transrectal biopsy.
- Third, detailed procedural information, including the number of targeted biopsy cores and whether systematic sampling was performed, was unavailable.

- Fourth, longitudinal follow-up was not documented, particularly for patients with PI-RADS 5 lesions and benign histopathological findings.
- Finally, incomplete complication documentation limits the assessment of procedural safety.

These limitations indicate that the findings should be interpreted as preliminary descriptive observations rather than evidence of diagnostic accuracy or comparative effectiveness.

5 CONCLUSION

Transperineal MRI–ultrasound fusion-guided prostate biopsy using the KOELIS Trinity system was used to sample MRI-identified prostatic lesions in six patients under general anesthesia.

Prostatic adenocarcinoma was identified in two patients, both classified as ISUP grade group 1, while four patients had benign histopathological findings.

The presence of benign biopsy findings in two PI-RADS 5 lesions highlights the diagnostic challenges associated with radiological–histopathological discordance and the importance of appropriate clinical follow-up.

This preliminary experience supports further investigation of the technique in larger, systematically documented cohorts with standardized biopsy protocols, complete complication assessment, and longitudinal follow-up.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

Disclosure of conflict of interest

The authors declare no conflicts of interest, including any financial or professional relationships with KOELIS.

Statement of informed consent

Informed consent for publication of anonymized clinical information and imaging data was obtained from the patient, in accordance with institutional requirements.

Author contributions

All authors contributed to the preparation of the manuscript. All authors reviewed and approved the final version of the manuscript.

Data availability

The data supporting this report are available from the corresponding author upon reasonable request, subject to institutional policies and patient confidentiality requirements.

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