

Comparison of the diagnostic performance of MRI/ultrasound fusion-guided prostate biopsy versus ultrasound-guided prostate biopsy in patients with suspected prostate cancer

Comparación del rendimiento diagnóstico de la biopsia de próstata guiada por fusión RM/ecografía respecto a la biopsia de próstata guiada por ecografía en pacientes con sospecha de cáncer de próstata

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Summary

Introduction: Transrectal ultrasound-guided prostate biopsy has been the diagnostic standard for prostate cancer. However, this technique may miss clinically significant lesions. MRI/ultrasound fusion-guided biopsy allows targeted sampling of suspicious lesions previously identified by imaging. ***Objective:*** To evaluate the diagnostic performance of MRI/ultrasound fusion-guided prostate biopsy compared to conventional ultrasound-guided biopsy for the detection of clinically significant prostate cancer. ***Methods:*** A cross-sectional diagnostic validation study was conducted at a specialized imaging center in Medellín, Colombia, between January and December 2020. A total of 115 patients with suspected prostate cancer (PSA > 3 ng/mL or abnormal digital rectal exam) underwent multiparametric MRI followed by both fusion-guided and conventional biopsies. The reference standard was the conventional biopsy. Sensitivity, specificity, and predictive values were calculated, and the detection of clinically significant cancer (Gleason ≥7) was compared between techniques. ***Results:*** A total of 115 patients with suspicious findings on multiparametric MRI (PI-RADS ≥ 3) were included in the analysis. The MRI/ultrasound fusion-guided biopsy demonstrated a sensitivity of 91.7 %, specificity of 81.6 %, positive predictive value (PPV) of 36.7 %, and negative predictive value (NPV) of 98.2 %. Clinically significant cancer (Gleason ≥ 7) was detected in 26.1 % of cases with fusion biopsy, compared to 10.4 % with the conventional technique, with a statistically significant difference ($p < 0.0001$). ***Conclusion:*** MRI/ultrasound fusion-guided prostate biopsy improves the detection of high-grade carcinomas compared to the conventional technique. Its use may enhance early diagnosis and timely treatment of clinically significant prostate cancer.

Resumen

Introducción: La biopsia prostática guiada por ecografía transrectal ha sido el estándar diagnóstico para el cáncer de próstata. Sin embargo, esta técnica puede omitir lesiones clínicamente significativas. La biopsia por fusión de resonancia magnética (RM) con ecografía permite dirigir las muestras hacia lesiones sospechosas previamente identificadas por imagen. ***Objetivo:*** Evaluar el rendimiento diagnóstico de la biopsia prostática guiada por fusión RM/ecografía en comparación con la biopsia convencional guiada por ecografía para la detección de cáncer de próstata clínicamente significativo. ***Metodología:*** Estudio transversal de validación diagnóstica realizado en un centro especializado en imágenes de Medellín, Colombia, entre enero y diciembre de 2020. Se incluyeron 115 pacientes con sospecha de cáncer prostático (PSA > 3 ng/mL o tacto rectal alterado), quienes se sometieron a RM multiparamétrica y posteriormente a biopsia con y sin fusión. La referencia fue la biopsia convencional. Se calcularon sensibilidad, especificidad, valores predictivos y se comparó la detección de cáncer clínicamente significativo (Gleason ≥ 7). ***Resultados:*** Se analizaron 115 pacientes con hallazgos sospechosos en la resonancia magnética multiparamétrica (PI-RADS ≥ 3). La biopsia prostática guiada por fusión RM/ecografía mostró una sensibilidad (S) del 91,7 %, una especificidad (E) del 81,6 %, un valor predictivo positivo (VPP) del 36,7 % y un valor predictivo negativo (VPN) del 98,2 %. El cáncer clínicamente significativo (Gleason ≥ 7) se detectó en el 26,1 % de los casos con biopsia por fusión, frente al

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10,4 % con la técnica convencional, con una diferencia estadísticamente significativa (p < 0,0001). ***Conclusión:*** La biopsia prostática guiada por fusión RM/ecografía mejora la detección de carcinomas de alto grado en comparación con la técnica convencional. Su uso podría optimizar el diagnóstico precoz y el tratamiento oportuno del cáncer de próstata clínicamente significativo.

Introduction

Prostate cancer is the most common malignant neoplasm in men and the second leading cause of cancer-related death in this group in Colombia, and it represents one of the major public health problems among the male population (1). Globally, there are an estimated 1,300,000 new cases and more than 359,000 deaths annually associated with this disease, making it the fifth leading cause of cancer-related mortality in men (2).

Currently, screening is based on measuring prostate-specific antigen (PSA) levels and digital rectal examination (DRE), tools that allow for the detection of clinically silent cases (3). However, to confirm the diagnosis, a prostate biopsy is required, which has traditionally been performed using transrectal ultrasound guidance (TRUS), considered to this day the gold standard. The method involves obtaining prostate tissue samples using a transrectal ultrasound-guided Trucut—the number of samples per session varies, with 10 to 12 cylinders currently being the standard—(4–6).

One of the main limitations of this technique is that between 25% and 40% of clinically significant cancers go undetected, especially those located in the anterior or middle zones of the gland, due to the random nature of the sampling (4–10). Additionally, taking multiple samples from different regions of the prostate reduces the likelihood of obtaining samples consisting solely of non-pathological tissue. However, a large number of lesions are found in the anterior and mid-line regions of the prostate gland, and the "blind" nature of the procedure, combined with the scarcity of anterior and mid-line glandular samples, explains the high rate of false negatives, which can reach as high as 47% (11–17).

Multiparametric magnetic resonance imaging (mpMRI) allows for more accurate visualization of suspicious lesions, and when combined with ultrasound using fusion software, it enables targeted biopsies, which increases the detection rate of clinically significant cancer by approximately 30% compared to the standard technique and reduces the detection of low-risk tumors by 17% (8, 14).

The Gleason scoring system remains the primary histopathological criterion for classifying cancer risk, and a score of 7 or higher is considered clinically significant, especially if it corresponds to a 4+3 pattern or higher, according to the recommendations of the International Society of Urological Pathology (ISUP) (9, 15).

Previous studies have shown that MRI/ultrasound fusion-guided biopsy not only improves the detection of high-grade lesions but also yields cylinders with higher tumor content and a lower false-negative rate compared with conventional random biopsy (10–17).

The objective of this study was to evaluate the diagnostic performance of MRI/ultrasound fusion-guided prostate biopsy compared with conventional transrectal ultrasound-guided biopsy—using the latter as the gold standard—for the detection of clinically significant prostate cancer in clinically suspected patients treated at a specialized diagnostic imaging center.

Materials and Methods

Study Design and Clinical Setting

A cross-sectional diagnostic test validation study was conducted at a single center specializing in diagnostic imaging in Medellín, Colombia, between January and December 2020. The study was approved by the ethics committee of the School of Health Sciences at the Universidad Pontificia Bolivariana (Minutes No. 23 of December 9, 2019), as well as by the institutional committee of the healthcare center where the procedures were performed. All participants signed an informed consent form before being included in the study, which was conducted in accordance with the principles of the Declaration of Helsinki and following the recommendations of the START standards for MRI-guided biopsy studies (18, 19).

Participants

The study included male patients with clinically suspected prostate cancer—defined as a PSA > 3 ng/mL or an abnormal finding on digital rectal examination—who were referred for a prostate biopsy. None of the patients had participated in previous cohorts related to MRI-guided biopsy techniques.

Exclusion criteria included contraindications for MRI—claustrophobia, implanted metallic or electronic devices—situations that would prevent the biopsy from being performed—bleeding diathesis, active urinary tract infection, or a history of anorectal surgery—nonadherence to the antibiotic regimen, or abnormalities in coagulation tests.

Diagnostic procedures

- **Magnetic resonance imaging:** All patients initially underwent a prostate MRI, performed using Siemens MAGNETOM Amira® 1.5T and MAGNETOM Skyra® 3T systems, with a whole-body coil. The protocol included T2-weighted sequences in all three planes, diffusion sequences (B-values: 0, 50, and 1000) with apparent diffusion coefficient (ADC) mapping, and did not involve the use of an endorectal coil or intravenous contrast medium.

  The images were interpreted by radiologists specializing in body imaging (with 10 and 15 years of experience), who had access to the clinical history and classified the lesions using the PI-RADS v2.1 scale (20, 21).

- **Biopsy protocol:** sequential prostate biopsies were taken during the same outpatient procedure. First, a radiologist without access to the MRI images performed a random systematic biopsy guided by transrectal ultrasound (TRUS) using a Toshiba Aplio a450 ultrasound scanner to obtain between 10 and 12 cylinders from the base, middle region, and apex of both lobes.

Subsequently, during the same anesthesia session, a second radiologist, who was aware of the MRI findings, guided an MRI/ultrasound fusion-guided biopsy using the trakSTAR® 3D Guidance software integrated into the same ultrasound scanner. Rigid multivolume registration was performed on axial or sagittal T2-weighted sequences and diffusion sequences with an ADC map to obtain between 4 and 6 cylinders from the suspicious lesion.

The samples were sent to a specialized external laboratory, labeled separately as "fusion biopsy" and "non-fusion biopsy." An example of how the biopsies were obtained is shown in Figure 1.

Study Variables

The variables included:

- **Outcome variable:** clinically significant cancer (defined as a Gleason score ≥ 7).
- **Independent variables:** type of biopsy (with or without fusion), PI-RADS results on MRI, PSA levels, and digital rectal examination findings.
- **Control variables:** age, prostate volume, lesion location, and size.
- **Histological classification:** based on Gleason score, divided into low-risk (Gleason ≤ 6), intermediate-risk (7 = 3+4), and high-risk (≥ 7 = 4+3 or higher).

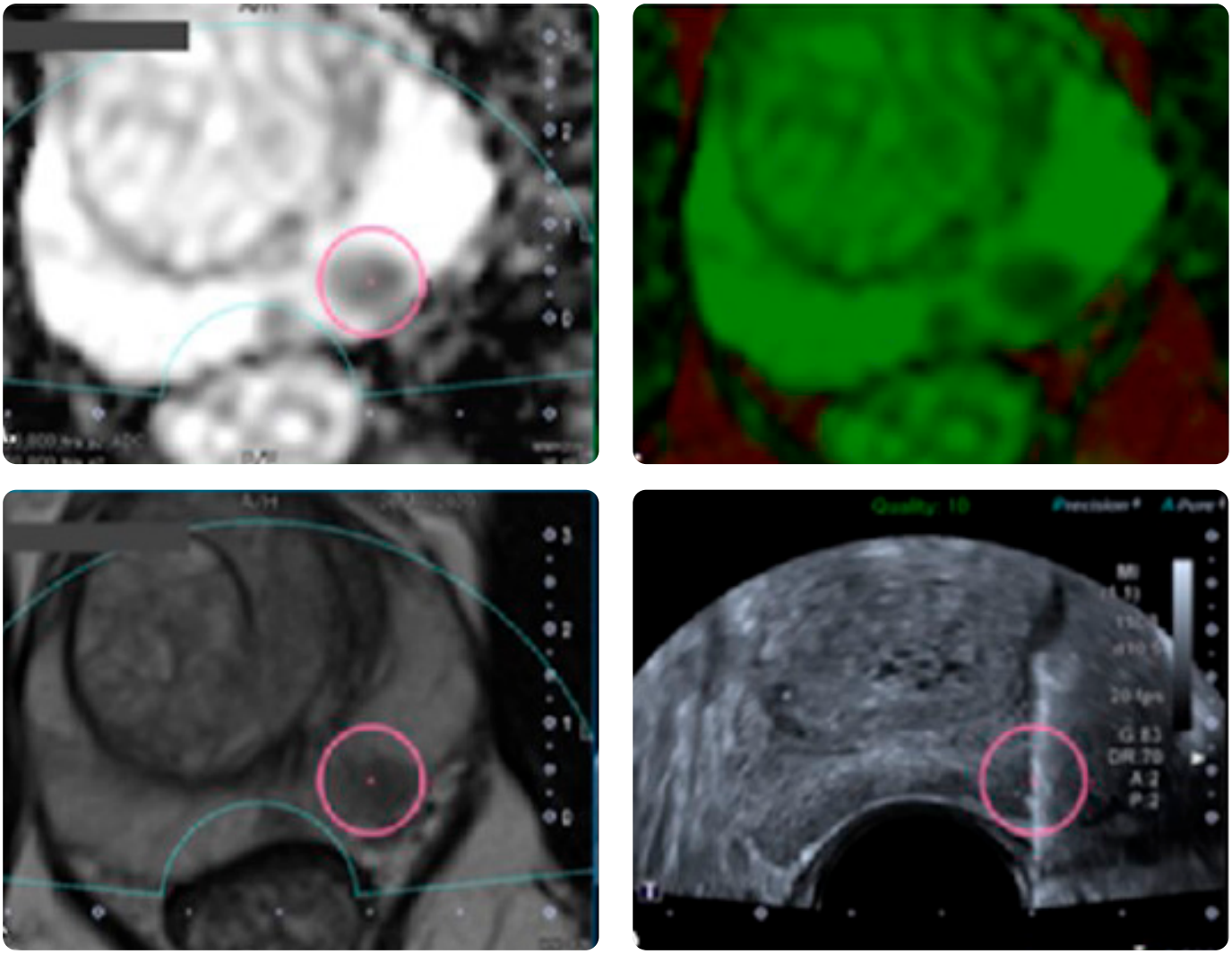


Figure 1. MRI/ultrasound-guided biopsy. A patient underwent an MRI/ultrasound-guided biopsy; six cylinders were obtained from the lesion visible on MRI (not visible on ultrasound). All cylinders were involved—between 70–100% of the cylinder—with a Gleason score of 4+3. Random cylinders were also obtained from both sides; none of these showed evidence of carcinoma on histological examination. MRI sequences from the simplified protocol: a) ADC diffusion map; b) color-coded ADC map; c) axial T2-weighted image; d) ultrasound image of an axial section of the prostate gland; the pink circle corresponds to the lesion identified on MRI, and the echogenic line within it corresponds to the biopsy needle.

Data Management and Bias Control

Clinical and sociodemographic data were collected prospectively by two independent investigators using a structured database in Microsoft Excel. To minimize observer bias, the radiologist performing the systematic biopsy was blinded to the results of the previous MRI, and the targeted biopsy was performed by another radiologist immediately afterward. The samples were labeled and coded to reduce bias in histological interpretation; however, complete blinding was not possible due to departmental conditions. Independent pathologists, who were unaware of the study hypothesis, performed the readings.

Sample Size Calculation

The sample size was not based on a prior probabilistic calculation; rather, all consecutive patients who met the inclusion criteria during the study period (January through December 2020) were included, in order to ensure the logistical feasibility of the study and adequate statistical power to detect clinically significant differences.

Statistical analysis

Qualitative variables were described using absolute and relative frequencies; quantitative variables were summarized using means and standard deviations or medians and ranges, depending on their distribution.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated with 95% confidence intervals, using conventional ultrasound-guided biopsy as the reference test.

To compare the proportion of clinically significant cancers detected by each technique, the McNemar test was applied. Analyses were performed using STATA software, version 15.0.

Results

Patient Involvement

During the study period (January through December 2020), 147 patients with suspected prostate cancer were referred for biopsy. Of these, 12 patients (8.2%) were excluded due to a lack of complete histological data, leaving 135 patients in the final cohort who underwent biopsy without fusion imaging. Of these 135, 20 patients with MRI studies showing no focal lesions (PI-RADS ≤ 2) did not undergo targeted biopsy and were therefore excluded from the comparative analysis. Finally, 115 patients with suspicious findings (PI-RADS 3 to 5) were included to evaluate the diagnostic performance of MRI/ultrasound-guided biopsy (Figure 2).

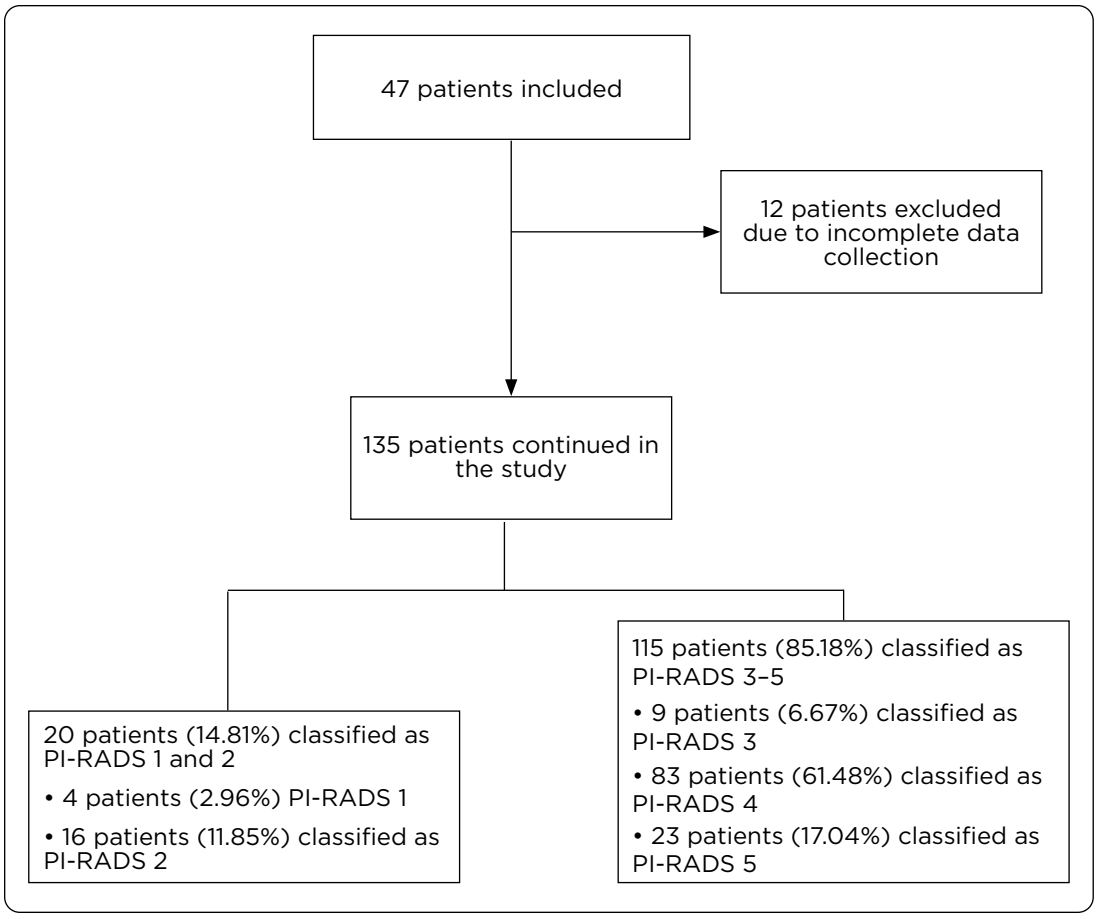


Figure 2. Enrollment and follow-up of patients during the study until the prostate MRI was performed.

Clinical and Demographic Characteristics

The mean age of the patients was 63.5 years (SD ± 8.2). 93.3% of the participants had a PSA level greater than 3 ng/mL, and 69.6% had an abnormal digital rectal exam. Socioeconomic stratum 3 (37.8%) was the most common. The distribution of PI-RADS categories was as follows: PI-RADS 3 (6.7%), PI-RADS 4 (61.5%), and PI-RADS 5 (17.0%).

Regarding biopsy findings without fusion imaging, 77.8% of patients were classified as benign, whereas with the fusion technique, this proportion was 57%. The average prostate volume was 47 grams (range 34–68), and the mean size of the suspicious lesion was 1.3 cm (range 0.55–2.0 cm). Lesions were predominantly located in the left lobe (37.1%) and were bilateral in 22.2% of cases. The main characteristics of these patients are summarized in Table 1.

Table 1. Sociodemographic and clinical characteristics of patients with suspected prostate cancer

Characteristics	Data (*n*=135)	
Age, mean ± SD	**63.5 ± 8.2**	
Socioeconomic status, *n* (%)	1	1 (0.7)
	2	11 (8.1)
	3	51 (37.8)
	4	19 (14.1)
	5	23 (17.0)
	6	8 (5.9)
	Not reported	22 (16.3)
Abnormal digital rectal exam (%)	Yes	94 (69.6)
	No	29 (21.5)
	Not reported	12 (8.9)
PSA (prostate-specific antigen in ng/mL), *n* (%)	Greater than 3	126 (93.3)
	Less than 3	8 (5.9)
	Not reported	1 (0.7)
PI-RADS, *n* (%)	1	4 (3.0)
	2	16 (11.9)
	3	9 (6.7)
	4	83 (61.5)
	5	23 (17.0)
Gleason score based on biopsy without fusion, *n* (%)	Benign	105 (77.8)
	6 (3+3)	15 (11.1)
	7(3+4)	4 (3.0)
	7 (4+3)	6 (4.4)
	8 (4+4)	2 (1.5)
	9 (4+5)	3 (2.2)
	9 (5+4)	0
Gleason score based on biopsy with fusion, *n* (%)	Benign	77 (57.0)
	6 (3+3)	25 (18.5)
	7(3+4)	12 (8.9)
	7 (4+3)	13 (9.4)
	8 (4+4)	5 (3.7)
	9 (4+5)	2 (1.5)
	9 (5+4)	1 (0.7)
Clinically significant without fusion, *n* (%)	Yes	15 (11.1)
	No	120 (88.9)
Clinically significant with fusion, *n* (%)	Yes	33 (24.4)
	No	101 (75.6)

Prostatitis, *n* (%)	Yes	30 (22.2)
	No	104 (77.0)
	Not available	1 (0.7)
Lateralization, *n* (%)	Left	50 (37.1)
	Right	37 (27.4)
	Central	1 (0.7)
	Bilateral	30 (22.2)
	No lesion	17 (12.6)
Type of involvement, *n* (%)	Extracapsular extension	11 (8.15)
	Seminal vesicles	5 (3.7)
	Lymphadenopathy	3 (2.22)
Glandular volume in grams, Mean (range)	47 (34-68)	
Lesion size in cm, Mean (range)	1.3 (0.55-2)	

Detection of clinically significant cancer

The biopsy without fusion imaging detected clinically significant cancer (Gleason ≥ 7) in 12 patients (10.4%), while the biopsy with fusion imaging identified it in 30 patients (26.1%). This difference was statistically significant (McNemar's test, $p < 0.0001$), with a relative detection ratio of 2.5 (95% CI: 1.6–4.0), indicating that the fusion technique detected 2.5 times more high-grade cancers than conventional biopsy (Table 2).

The sensitivity of fusion-guided biopsy was 91.7% (95% CI: 86.6–96.7), the specificity was 81.6% (95% CI: 74.5–88.6), the positive predictive value (PPV) was 36.7% (95% CI: 27.9–45.5), and the negative predictive value (NPV) was 98.2% (95% CI: 96.9–100). These results show that the test has a high ability to rule out disease when the result is negative, but a limited PPV, as has been reported in the literature (22, 23).

Table 2. Detection of high-risk cancers using fusion biopsy versus non-fusion biopsy

Fusion biopsy	Non-fusion biopsy		Total
	High risk (Gleason ≥ 7 [3+4])	Benign and low risk (Gleason ≤ 6 [3+3])	
High-risk (Gleason ≥ 7 [3+4])	11	19	30
Benign and low-risk (Gleason ≤ 6 [3+3])	1	84	85
Total	12	103	115

Comparison of Gleason Scores Across Techniques

The distribution of Gleason scores showed significant differences between the two techniques. In the biopsy without fusion, 77.4% of patients were classified as benign and only 8.7% as high-grade (Gleason ≥ 7). In contrast, fusion-guided biopsy reduced the proportion of benign cases to 53.9% and increased the detection rate of high-grade tumors to 17.4%. Additionally, 19 patients were reclassified as high-grade using the fusion technique, after having been identified as benign or low-grade by the conventional technique (Table 3).

Table 3. Comparison of Gleason scores obtained from biopsies without fusion and biopsies with fusion

Gleason score	Biopsy without fusion *n* (%)	Biopsy with fusion *n* (%)
Benign (not cancer)	89 (77.4)	62 (53.9)
6 (3+3)	14 (12.2)	23 (20.0)
7 (3+4)	2 (1.7)	10 (8.7)
≥ (4+3)	10 (8.7)	20 (17.4)

Discussion

Main findings

This cross-sectional study evaluated the diagnostic performance of MRI/ultrasound fusion-guided prostate biopsy, using conventional transrectal ultrasound-guided biopsy as the reference. The fusion technique was found to detect a greater number of clinically significant cancers (Gleason score ≥ 7), with a sensitivity of 91.7% and a negative predictive value (NPV) of 98.2%, suggesting that this technique may be an effective tool for improving the identification of clinically relevant tumors in patients with clinically suspected prostate cancer (18–21).

Comparison with the literature and possible interpretation

The results of the study are consistent with the findings reported by Siddiqui et al. (14), who found that fusion-guided biopsy detects more high-grade tumors compared to the conventional systematic technique. Similarly, the study by Cornud et al. (17) demonstrated that image-guided fusion significantly increases the detection rate of high-risk lesions, reinforcing the added value of this methodology in clinical practice.

Shoot et al. (22) and Hashim et al. (23) also reported sensitivity values close to 90% for the fusion technique, similar to those obtained in this study. However, methodological differences—such as the use of transperineal mapping biopsy in Hashim's study—and stricter inclusion criteria (e.g., PSA levels ≥ 15 ng/mL) must be considered when interpreting the results.

Additionally, fusion-guided biopsy was found to reclassify 19 patients who had been considered benign or low-grade by the conventional technique, which substantially increases the detection of significant disease. This translates to better therapeutic targeting and a potential reduction in undertreatment among patients at actual oncological risk.

It should be noted that, although a high detection rate of low-grade carcinomas (73.9%) was observed with the fusion technique in this cohort, this finding differs from that reported in other studies in which this technique has shown a lower detection rate of low-risk lesions (15, 18). This difference could be explained by factors related to tumor burden, the population profile, or the operators' experience. In any case, additional evidence is needed to clarify whether fusion imaging actually improves clinical specificity, in order to avoid the overdiagnosis of indolent tumors (asymptomatic, low-grade tumors with a low probability of growing or metastasizing).

Study limitations

Among the main limitations of this study is the sample size, which, while sufficient for exploratory analyses, could be considered too small to evaluate results in subgroups or to adjust for multiple covariates. Furthermore, although we attempted to minimize observer bias by separating the application of each technique, it was impossible to completely blind the pathology team to the origin of the samples, since they were labeled by technique type (fusion or conventional), which could introduce interpretive bias.

Another limitation was the inclusion of some patients with negative MRI findings (PI-RADS ≤ 2), who were systematically biopsied based on clinical criteria (elevated PSA or abnormal digital rectal exam). However, these cases were excluded from the comparative analysis to avoid biases related to the lack of a target lesion for targeted biopsy.

Generalizability and external validity

The results presented here may be applicable to centers with similar technological resources, experience in prostate imaging, and access to fusion software. However, the reproducibility of the results may be affected by factors such as the operators' learning curve, the type of equipment used, and the demographic and clinical characteristics of the study population.

Conclusion

MRI/ultrasound fusion-guided prostate biopsy demonstrated superior diagnostic performance compared to conventional ultrasound-guided biopsy, particularly in the detection of clinically significant cancer. This technique showed high sensitivity and negative predictive value, allowing for more accurate identification of patients with high-grade carcinoma who could benefit from early diagnosis and timely treatment.

Incorporating fusion biopsy as a diagnostic tool in patients with suspicious MRI findings and high clinical risk could significantly improve the management of prostate cancer by reducing false negatives and potentially avoiding the overdiagnosis of clinically irrelevant lesions. Its phased implementation in specialized centers is recommended, accompanied by technical training and ongoing validation.

Studies with larger populations and prospective designs are needed to confirm these findings and evaluate the clinical impact and cost-effectiveness of this technique in real-world care settings.

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