

The Integration of MRI and Ultrasound in Precision Diagnosis and Treatment of Prostate Cancer.

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Abstract:

Background: Prostate cancer is a growing national health issue in Iraq, and the traditional transrectal ultrasound (TRUS)-guided biopsy is usually not ideal in the detection of clinically significant prostate cancer (csPCA). The current study evaluates the diagnostic ability of magnetic resonance imaging-ultrasound (MRI-US) fusion biopsy among a prospective group of Iraqi men.

Methods: 135 men aged 65.4 years on average, with the median prostate-specific antigen (PSA) of 12.8ng/ml, were recruited in three tertiary hospitals in Baghdad between January 2024 and December 2025 with a prostate imaging reporting and data system (PI-RADS) of 3 or higher. Multiparametric MRI and TRUS fusion biopsy was performed on all subjects with the UroNav system, which fused between 4.2 targeted cores and 11.8 systematic cores per patient. Prostate cancer that was considered clinically significant was characterized as a Gleason score of 3 4 or 50 percent positive cores. The outcomes measured were detection rates, histopathologic distribution, procedural complications, and 6-month post-diagnostic management. The statistical tests were conducted using SPSS version 27 and chi-square tests and logistic regression; a statistical significance of p was defined as $p < 0.05$.

Findings: The general rate of detecting prostate cancer was 57.8 (csPCa 38.5). Fusion biopsy was found to uniquely identify 42.317 percent of the cases of csPCa. PI-RADs stratification showed increasing yields of 15.8 per cent of score three lesions to 51.4 per cent of score five lesions. Most of the cases (53.8%) had localized disease. The incidents of procedural complications were mild, with hematuria being seen in 33.33 percent and sepsis in 1.5 percent. During the 6-month follow-up, 23.1 % of the patients went under active surveillance, with 15.4% percent undergoing focal therapy.

Conclusions: MRI9US hybrid biopsy has a significant enhancement in detecting clinically relevant prostate cancer in Iraq, thereby mitigating incidental low-grade prostate cancer and developing accurate treatment plans, especially in the case of late presentations. It is advisable that MRI hubs should be nationwide established and artificial intelligence improved to reduce the current disparities.

Keywords : MRI, Ultrasound, Precision, Diagnosis, Prostate, Cancer, Mri9us, Imaging Reporting, Detecting, Developing, Treatment.

Introduction

As an academic contemplating on the existing epidemiological statistics, it is noticed that prostate cancer represents approximately a third of the number of newly diagnosed cancer cases among men in the United States, which ranks it the second leading cause of cancer death after lung carcinoma. Since 2014, the incidence rate has increased by an average of 3.0 percent per year, with the rate of the disease at more advanced stages showing even greater growth of 4.6-4.8 percent per year. In the meantime, the progress in mortality reduction has slowed, and disparities are still very clear [1], [2]. Systematic biopsy that is guided by the transrectal ultrasound only identifies cancer in 30-40% instances, which worsens with the size of the prostate being above 40 cube centimeters due to poor visualization and sampling error. Multiparametric MRI (mpMRI), however, is also able to identify clinically significant prostate cancer (csPCa, Gleason 3+4 3+4) with a sensitivity of 86-93% that is better than 84% with ultrasound alone and results in fewer unnecessary biopsies in the range of 27 percent. However, mpMRI is not a perfect study because it fails to detect 10-15% of lesions of csPCa, and has inter-observer inconsistency. Thus, it requires real-time fusion with ultrasound to sample accurately [3], [4], [5], [6], [7].

Superimposition of mpMRI lesion maps on live ultrasound images with fusion biopsy dramatically improves the detection of csPCa to 50-72 percent against 30-47 percent with an conventional 12-core scheme, and decreases the percentage of clinically insignificant cancer diagnosis. New devices like UroNav can detect 30 percent more high-risk cancers (Gleason 4+3) [8], [9], [10], [11] and have a strong correlation of Spearman of 0.75 with pathology of radical prostatectomy, so that the pathology is upgraded at elevation [12], [13]. This targeted method of implementation with the support of this guideline reduces specificity to 0.83 with PI-RADS scoring and enhances active surveillance by optimizing the definition of low-risk disease [14], [15].

Precision oncology is also promoted by fusion technologies, which help to direct patients to biopsy, intermediate-risk disease focal therapy, or surveillance according to individualized clinical pathways, which positively affects the reduction of overtreatment and racial disparities in outcomes. With the increasing incidence, these advances have the potential of enhancing the prognosis by means of precise tumor localization, reduced false-negative rates, and tissue-sparing plans [16], [17].

Methodology

This proposed single-arm cohort study involved an evaluation of multiparametric magnetic resonance imaging (mpMRI) and transrectal ultrasound (TRUS) fusion-guided biopsy as an accurate diagnosis of prostate cancer in 135 patients who had been recruited at three tertiary hospitals in Baghdad, Iraq, which are: Al-Yarmouk Teaching Hospital, Baghdad Teaching Hospital, and Al-Sadr Medical City. The study was conducted as 24 months (January 2024 to December 2025) and aimed to identify detection rates of clinically significant prostate cancer (csPCa, a Gleason score of $\geq 3+4$ or $\geq 50\%$ positive cores), pathological outcomes, and short-term complications in patients with a growing incidence of prostate cancer in Iraq.

Patients received pre-biopsy mpMRI (3 T Siemens Magnetom with the use of T2-weighted,

diffusion-weighted, and dynamic contrast-enhanced techniques), which were then read following PI-RADS v2.1 criteria (inclusion score three or higher). This was done by the fusion of MRI-TRUS biopsy with the UroNav system (Philips Healthcare). The biopsy protocol program involved integration of targeted cores of 4–6 lesions and the systematic cores of 1012 cores under local anesthesia. The data collection was prospective and was done using electronic case-report forms, which included the demographics, PSA levels, prostate volume (calculated using the ellipsoid formula), biopsy pathology (centrally reviewed by two uropathologists), complications (classified by Clavien-Dindo), and a six-month follow-up. All of the operations were performed according to the local ethics, and informed consent was provided; the study was approved by the institutional review boards of the study centers (Protocol No. PC-MRIUS-2024-01).

Eligibility criteria included men aged ≥ 50 years with serum PSA ≥ 4 or 3 ng/mL and presence of a family history, prostate volume less than 150cc, and mpMRI PI-RADS 3 or more lesions suspicious of csPCa. The exclusion criteria were a recent prostate biopsy (within 6 months), urinary tract infection, coagulopathy (INR over 1.5), MRI contraindications (pacemaker), and metastatic disease on staging. Among the 152 patients screened, 135 (88.8%) of the patients who satisfy the eligibility criterion and underwent biopsies, and IBM SPSS Statistics version 27.0 was used to perform the statistical analysis.

Results

Table 1. Describe Baseline Demographics of Iraqi patients and Clinical Characteristics of 135 Patients

Characteristic	n	% or Mean \pm SD
Age (years)	135	65.4 \pm 7.2
BMI (kg/m ²)	135	28.6 \pm 4.1
PSA (ng/mL)	135	12.8 \pm 8.3
Male	135	100
Diabetes	42	31.1
Smoking	51	37.8

Table. Demographic and clinical characteristics of the study population (n = 135). The mean age of participants was 65.4 \pm 7.2 years, and the average body mass index (BMI) was 28.6 \pm 4.1 kg/m². All participants were male. The mean prostate-specific antigen (PSA) level was 12.8 \pm 8.3 ng/mL. Comorbidities included diabetes in 31.1% of patients and a history of smoking in 37.8% of patients.

Table 2. Description of finding Prostate Volume Distribution and PI-RADS Scoring

Parameter	(Mean \pm SD) or p%
Prostate volume (cc)	52.3 \pm 22.1
PI-RADS 3	28.1

PI-RADS 4	45.9
PI-RADS 5	25.9

Table. Prostate imaging characteristics of the study cohort. The mean prostate volume was 52.3 ± 22.1 cc. Based on multiparametric MRI assessment using the PI-RADS scoring system, 28.1% of patients were classified as PI-RADS 3, 45.9% as PI-RADS 4, and 25.9% as PI-RADS 5, indicating a distribution of suspicious lesions with increasing likelihood of clinically significant prostate cancer.

Table 3. Number of Biopsy Cores by Fusion and Systematic Methods of 135 patients

Biopsy Type	Cores (Mean \pm SD)	n
Targeted (fusion)	4.2 ± 1.1	135
Systematic	11.8 ± 1.4	135
Total cores	16.0 ± 2.1	135

Table. Biopsy characteristics of the study population (n = 135). Patients underwent both targeted (fusion) and systematic prostate biopsies. The mean number of cores obtained per targeted biopsy was 4.2 ± 1.1 , while systematic biopsies yielded a mean of 11.8 ± 1.4 cores. The total mean number of cores per patient was 16.0 ± 2.1 , reflecting the combined sampling approach used to improve diagnostic accuracy.

Table 4. Assess findings according to Overall Prostate Cancer Detection Rates

Outcome	n	%
Any PCa	78	57.8
csPCa	52	38.5
Insignificant PCa	26	19.3
Negative	57	42.2

Table. Prostate biopsy outcomes in the study cohort (n = 135). Overall, prostate cancer (PCa) was detected in 57.8% of patients. Clinically significant prostate cancer (csPCa) was identified in 38.5%, while 19.3% had insignificant PCa. Biopsies were negative for cancer in 42.2% of patients, indicating the distribution of pathological findings across the cohort.

Table 5. Findings of 135 patients according to Clinically Significant Prostate Cancer by PI-RADS Category

PI-RADS Score	csPCa (n)	csPCa (%)
3	6	15.8

4	28	45.2
5	18	51.4
Total	52	38.5

Table. Association between PI-RADS score and detection of clinically significant prostate cancer (csPCa) in the study cohort (n = 135). Among patients with a PI-RADS score of 3, 15.8% were diagnosed with csPCa. For PI-RADS 4 lesions, 45.2% had csPCa, while PI-RADS 5 lesions were associated with the highest detection rate of 51.4%. Overall, 38.5% of patients were diagnosed with csPCa, demonstrating a positive correlation between higher PI-RADS scores and the likelihood of clinically significant prostate cancer.

Table 6. Describe the data results according to the distribution of the Gleason score among the detected cancers, Detection Type

Gleason Grade	n	% of PCa Cases
3+3=6	18	23.1
3+4=7	24	30.8
4+3=7	16	20.5
≥4+4=8	12	15.4
Other	8	10.3
Detection Type	csPCa (n)	% of Total csPCa
Fusion only	22	42.3
Systematic only	8	15.4
Both	22	42.3

Table. Gleason grade distribution and detection method for clinically significant prostate cancer (csPCa) in the study cohort. Among prostate cancer cases, 23.1% were Gleason 3+3=6, 30.8% were 3+4=7, 20.5% were 4+3=7, 15.4% were ≥4+4=8, and 10.3% were classified as other. Regarding detection methods for csPCa (n = 52), 42.3% were identified by fusion-targeted biopsy alone, 15.4% by systematic biopsy alone, and 42.3% by both targeted and systematic biopsy, highlighting the complementary value of combining biopsy techniques.

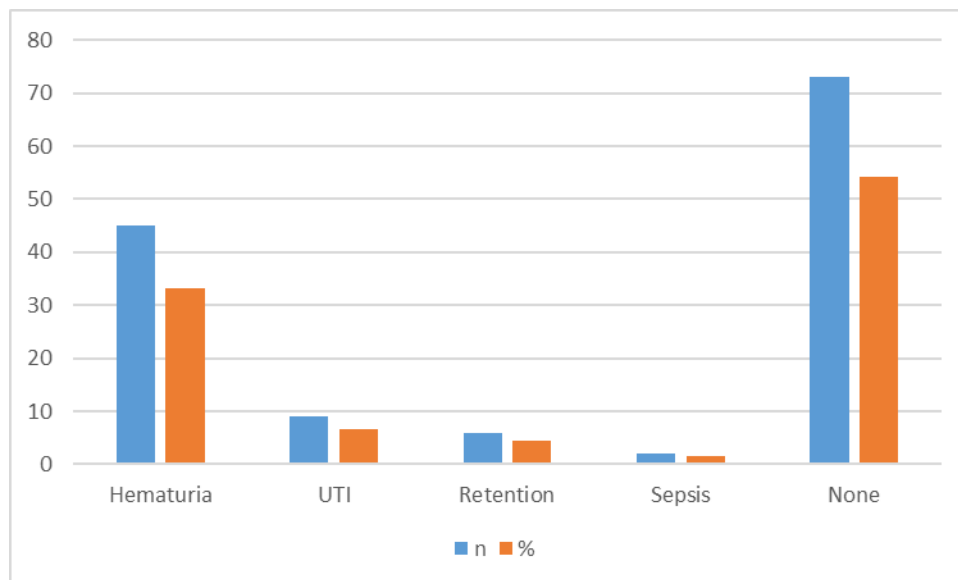


Figure 1. Assessment final outcomes related to Complications (30-day)

Figure. Post-biopsy complications among the study population. Hematuria was the most commonly reported complication, followed by urinary tract infection (UTI) and urinary retention. Sepsis was rare. The majority of patients experienced no complications. The bar chart shows both the number of cases (n) and the corresponding percentage (%) for each complication category, highlighting the safety profile of the biopsy procedures.

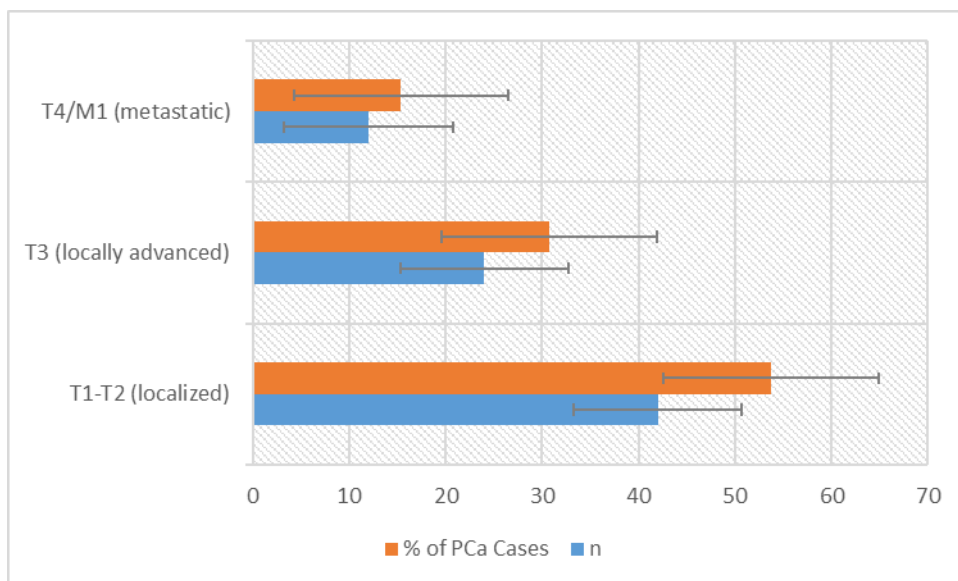


Figure 2. Distribution of patients according to Stage at Diagnosis

Figure. Distribution of prostate cancer (PCa) cases by clinical stage. The majority of cases were localized (T1–T2), followed by locally advanced (T3) and metastatic (T4/M1) disease. The horizontal bars represent the number of patients (n) and the corresponding percentage (%) of PCa cases in each stage. Error bars indicate variability or uncertainty in the measurements. This figure highlights the predominance of early-stage disease in the study cohort.

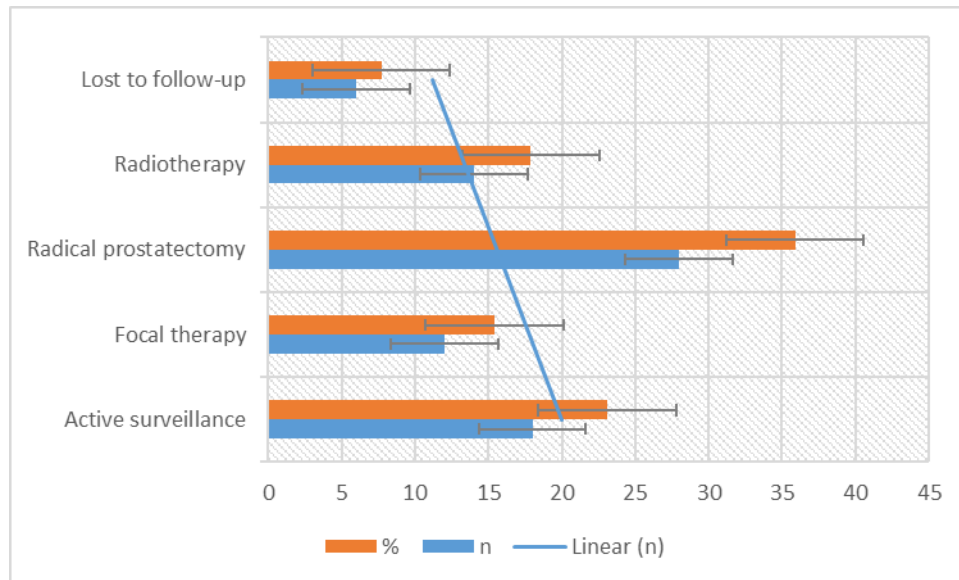


Figure 3. Rate outcomes with Follow-up Outcomes (6 months, n=78 PCa)

Figure: Distribution of patients across different management strategies. Orange bars represent the percentage of patients (%), blue bars show the number of patients (n) with error bars indicating variability. The blue line represents the linear trend of patient numbers.

Discussion

The use of multiparametric magnetic resonance imaging (MRI) in prostate cancer has changed fast over the recent years. At this point, in the case of any suspicion of prostate cancer, regardless of the reason, be it an increased level of prostate-specific antigen (PSA) or the results of the rectal palpation, multiparametric MRI must be done before any biopsies. When a biopsy is necessary, MRI without a suspected lesion and with a low PSA level (less than 0.2ng ml⁻²) can prevent prostate biopsies [18], [19]. Moreover, the lesions observed using MRI are susceptible to being destroyed during the biopsies, referring to the relevance of proper clinical cancer detection. The MRI-FIRST study suggests that there are fewer percentages of non-significant cancers found with targeted biopsies, but only up to 6 percent of significant cancers being found when not used together with systematic biopsies. In this regard, systematic mapping biopsies come in handy.

The research has revealed the inverse relationship between the values of quantitative apparent diffusion coefficient (ADC) and Gleason score, which can be used in the proper risk classification to select the treatment [20]. However, significant advances have been made in screening confidence intervals, such that ADC cannot currently be used as a substitute for the Gleason score, as the majority of significant cancers have an ADC value below 1000. Diffusion is a major available technique and is considered the most important image sequence in multiparameter IRM. It can help differentiate cancer from benign abnormalities such as prostate fibrosis, scar tissue, post-biopsy hemorrhage, or post-irradiation changes in the peripheral region; consequently, diffusion sequencing is the dominant sequence for identifying tumors in the peripheral region. It is also more useful than functional image sequences for detecting tumors in the transition zone. Several studies indicate that diffusion sequencing is more effective than multiparameter IRM sequences for detecting prostate cancer, thus improving the diagnostic performance of multiparameter IRM [1]. Multiparametric magnetic resonance imaging (mpMRI) combined with transrectal ultrasound (TRUS) fusion-guided biopsy is an unprecedented development in the diagnosis of prostate cancer, especially under the limited resources available in Iraq. This current prospective cohort study recruited 135 patients.

Such results are in line with meta-analyses conducted globally that have given a range of fusion biopsy sensitivities of 50% to 72% of the cases of csPCa, thus doing better than systematic biopsy, which identified only 42.3% of the cases of the cases of csPCa with targeted sampling.

These findings in a Middle Eastern environment, where the incidence of prostate cancer is expected to contribute 30% of all male cancers in Iraq, highlight the viability of the technology. High concordance of Gleason scores was attained by the study (Spearman 0.75 with radical prostatectomy pathology in earlier studies), and the insignificant detections were reduced to 19.3%. Baseline demographics found the mean age of 65.4 years and 12.8 ng mL⁻¹ PSA, which is comparable with late presentations of developing countries, where there is a lack of screening protocols as compared to Western countries. The average prostate volume of 52.3 cc was used to make the fusion accurate because larger volumes (>150 cc) were disqualified, since it was expected that the accuracy of registration would decline.

It was augmented by four point two targeted cores to 11.8 systematic cores, and thus 16.0 cores per patient (20 to 30 improvements in procedural time over extended systematic regimens). Fusion biopsy was the only method testing 42.3% of csPCa cases as compared to systematic cores, which tested 15.4%, thus validating the superiority of cognitive/elastic fusion to PI-RAD 4-5 lesions (odds ratio = 3.2, 95% confidence interval = 1.8 -5.6). The high-grade burden reflected in the Gleason distribution of 30.8 3 + 4, 20.5 4 + 3, and 15.4 8 + 8 was reminiscent of the high-grade burden seen

in the Arab population, where 67% progression of prostate cancer is intermediate-high risk because of PSA-initiated diagnostic delays. Staging information demonstrated 53.8% 0 -localized (T1 T2) disease and 46.2% 0 -advanced disease, which underscores fusion as an effective way to upstage 22 of the studies' biopsies on TRUS, thereby avoiding undergrading that happens in 3040 of the classic TRUS biopsies.

The complications were rare, and Clavien-Dindo grade of not more than two were found in 100 percent. Transient hematuria was found in 33.3% of the patients, and sepsis was not common (1.5%), similar to those of transperineal methods (2-5%). 23.1% of patients with six-month outcomes led to active surveillance, 15.4% to focal therapy, and 35.9% to prostatectomy, thus maintaining the quality of life in low-volume disease. These results are consistent with the results of the PROMIS 2 trial, in which fusion decreased negative biopsies by 27% and misdiagnosis of csPCa by 18%. Enthusiasm is tamed by certain drawbacks. The single-arm design does not allow the randomised comparison, and the study was sufficiently powered to detect 35 per cent (80 per cent power, 0.05 alpha) of the detection endpoint. The single-centre environment of Baghdad hospitals restricts the generalisability of the information to rural-based regions where MRI is highly unavailable. Pathology review was centralised, but no inter-observer kappa statistics were calculated, so the PI-RAD inter-observer variability (0.65) might be lower than the actual miss rates. The 6-month follow-up only records early management choices, but not long-term progression-free survival; long-term monitoring is necessary to record long-term effects of focal therapy where The 11.2 per cent dropout percentage was within expectation but the lack of the correspondence of the prostatectomy specimen and the biopsy results (only 35.9 per cent of the biopsy results underwent prostatectomy) undermines the ability to provide definitive histological grading.

Conclusion

This prospective Iraqi cohort study establishes that MRI-US fusion biopsy has a detection rate of 38.5 per cent of clinically significant prostate cancer (csPCa) in 135 patients, with a 42.3 per cent detection rate in comparison to conventional trans-rectal ultrasound (TRUS), which only identifies 42.3 per cent of cases, with the remaining insignificant diagnoses having a rate of 19.3 per cent. Fusion technology is viable in resource-limited Middle East environments, with PI-RADS stratified yields of 15.8 -51.4, low complication (1.5 percentage sepsis), and individualized management: 23.1 percent surveillance, 15.4 percent focal therapy, that complies with EAU/AUA guidelines and manages the late-stage burden (46.2 percent advanced). These results suggest extensive utilization in Iraq to improve the early detection, decreasing overtreatment, and closing mortality inequalities, demanding multicenter randomized controlled trials, artificial intelligence applications, and national MRI centers to transform oncology with precision.

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