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The role of multiparametric magnetic resonance in active surveillance of a low-risk prostate cancer cohort from clinical practice

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Abstract

Introduction: Active surveillance (AS) is considered a suitable management practice for those patients with low-risk prostate cancer (PCa). At present, however, the role of multiparametric magnetic resonance imaging (mpMRI) in AS protocols has not yet been clearly established.

Outcomes: To determine the role of mpMRI and its ability to detect significant prostate cancer (SigPCa) in PCa patients enrolled in AS protocols.

Materials and Methods: There were 229 patients enrolled in an AS protocol between 2011 and 2020 at Reina Sofía University Hospital. MRI interpretation was based on PIRADS v.1 or v.2/2.1 classification. Demographics, clinical, and analytical data were collected and analyzed. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for mpMRI in different scenarios. We defined SigPCa and reclassification/progression as a Gleason score (GS) ≥ 3 + 4, a clinical stage ≥T2b, or an increase in PCa volume. Kaplan–Meier and log-rank tests were used to estimate progression-free survival time.

Results: Median age was 69.02 (±7.73) at diagnosis, with a 0.15 (±0.08) PSA density (PSAD). Eighty-six patients were reclassified after confirmatory biopsy, with a suspicious mpMRI an indication for a clear reclassification and risk-predictor factor in disease progression ($p < 0.05$). During follow-up, 46 patients were changed from AS to active treatment mainly due to disease progression. Ninety patients underwent ≥2mpMRI during follow-up, with a median follow-up of 29 (15–49) months. Thirty-four patients had a baseline suspicious mpMRI (at diagnostic or confirmatory biopsy): 14 patients with a PIRADS 3 and 20 patients with ≥PIRADS 4. From 14 patients with a PIRADS 3 baseline mpMRI, 29% progressed radiologically, with a 50% progression rate versus 10% (1/10 patients) for those with similar or

decreased mpMRI risk. Of the 56 patients with a non-suspicious baseline mpMRI (PIRADS < 2), 14 patients (25%) had an increased degree of radiological suspicion, with a detection rate of SigPCa of 29%. The mpMRI NPV during follow-up was 0.91. **Conclusion:** A suspicious mpMRI increases the reclassification and disease progression risk during follow-up and plays an important role in monitoring biopsies. In addition, a high NPV at mpMRI follow-up can help to decrease the need to monitor biopsies during AS.

KEYWORDS
active surveillance, biopsy, multiparametric magnetic resonance, prostate cancer

1 | INTRODUCTION

Prostate cancer (PCa) is the second most common cancer in men worldwide.[1] The purpose of active surveillance (AS) is to reduce overtreatment, as well as invasive interventions with their inherent side effects, without compromising the survival of those patients with low-risk or intermediate-risk PCa, due to its natural history of a low progression rate after a decade of follow-up.[2–7]

The advent of multiparametric magnetic resonance imaging (mpMRI), with its high negative predictive value (NPV) and the performance of targeted biopsies versus systematic biopsy, has been shown to improve the detection rate of significant prostate cancer (SigPCa).[6,8] Therefore, its use is currently recommended at least before the confirmation/reclassification biopsy required to enroll in an AS program, which improves the risk stratification of PCa and the selection of patients included in the program.[9,10] In this regard, Hamoen et al.[11] concluded that a negative mpMRI within first year of AS program inclusion is the only predictor of a lower probability of reclassification during follow-up.

Patient follow-up during AS is not yet well established, with considerable heterogeneity between groups. Traditional protocols for AS are based on digital rectal examination (DRE), PSA, and monitoring prostate biopsies. However, poor patient tolerability, mainly due to repeated biopsies, is one of the main reasons AS protocols are abandoned [12–15]

The appearance of mpMRI has meant a change in AS protocols; however, there is still insufficient evidence that would obviate monitoring biopsies during follow-up.[16] Interobserver variability, lack of consensus among the AS protocols used, and lack of standardization of disease progression definitions in mpMRI may be some of the factors involved.[17]

With the aim of facilitating robust data collection in the mpMRI study, the PRECISE study proposed recommendations for radiological estimation in the sequential evaluation of PCa. The use of such a system when reporting MRI at baseline and during follow-up AS would allow the assessment of the natural progression of PCa on MRI.[18]

Finally, it should be noted that there is growing evidence suggesting that different factors may help in the decision about whether to repeat prostate biopsy during follow-up in conjunction with mpMRI. Some of these factors are age, number of previous negative biopsies, number of positive cores, PSA density (PSAD), PSA doubling time (PSAdt), and clinical stage.[19]

With this background, the aim of this study was to determine the role of mpMRI in AS protocols, as well as its ability to detect SigPCa during follow-up in clinical practice.

2 | MATERIALS AND METHODS

2.1 | Population and design

This was a retrospective study in an AS cohort collected between 2011 and 2020 in a single major center. All patients signed a specific consent for AS and data registry, and the study design was approved by the local ethics committee (N.269 Ref 3644).

The main inclusion criteria for AS protocol inclusion were PSA level <10 ng/mL or PSA level >10 ng/mL and PSAD ≤ 0.15; clinical stage <T2b; Gleason score < 3 + 4 on the initial biopsy; and three or fewer positive biopsy cores with less than 5 mm of a core affected on any biopsy.

A Gleason score ≥ 3 + 4, a clinical stage ≥ T2b, or an increase in the PCa volume (≥3 affected cores or >5 mm of the maximum affected core) were factors that defined SigPCa and triggered reclassification/progression to active treatment. If a target biopsy was positive, it was categorized as a single affected core.

The follow-up AS protocol recommended a confirmatory biopsy within the first year after diagnosis. Then, patients were evaluated according to DRE, PSA level, and repeated biopsies at 18 months, 42 months, and every 3 years thereafter. From 2015 onward, we introduced the mpMRI before confirmatory (around 6 months after the diagnosis) and follow-up biopsies. Based on the PIRADS category, we carried out systematic and/or fusion-targeted biopsy as previously described.[10] Strict adherence to the protocol was neither analyzed nor required for this study.

2.2 | Multiparametric magnetic resonance imaging

The mpMRI protocol included T1-weighted images (T1WI), T2-weighted images (T2WI), diffusion-weighted images (DWI), and

dynamic contrast-enhanced images (DCE) as previously described.[20] Lesions were classified according to PIRADS V.1 or V.2/V2.1 depending on the cohort period, respectively. Only one experienced radiologist reread the baseline and follow-up mpMRI in patients with a PIRADS score of ≥2 on mpMRI, who were included in the analysis for mpMRI monitoring.

2.3 | Prostate biopsy

Briefly, urologists performed biopsies using a transrectal approach in most cases, while a transperineal approach was used in a minority of the cohort. When no mpMRI was performed or when there was a PIRADS score <3, a systematic biopsy was performed with 12-core (for initial biopsy) or ≥18-core sextant biopsy during follow-up.

When mpMRI showed a PIRADS SCORE ≥ 3, the biopsy technique included an MRI-ultrasound fusion biopsy using a General Electric ultrasound machine (LOGIQ E9, GE Healthcare: Milwaukee, Wisconsin EE.UU, or Hitachi Medcom's BiopSee, FUJIFILM Healthcare: Europe, with real-time, sensor-based software, as previously described), as well as a standard 12-core biopsy in case of biopsy-naïve patients, and a 12–18-core biopsy in the context of follow-up.[21] For the targeted biopsy, a minimum of three cores were obtained. Two uro-pathologists who specialize in PCa evaluation reported biopsy findings using the ISUP recommendation according to the study period.[22,23]

2.4 | Statistical analysis

The main objective was to determine the role of mpMRI and the ability to diagnose a SigPCa in AS follow-up protocol patients.

The clinical and demographic characteristics of all patients were analyzed, including follow-up data. Qualitative variables are presented as absolute numbers and percentages. Quantitative variables are presented as mean values and SD.

Progression-free survival during follow-up, defined as the initiation of active treatment (radical prostatectomy, radiotherapy, etc.) stratified by mpMRI baseline category, was analyzed by Kaplan–Meier survival curves and log-rank tests.

The ability of follow-up mpMRI to diagnose SigPCa was summarized through the false-negative and false-positive rates (TFN and TFP, respectively) and predictive values (predictive positive value, VPP; predictive negative value, VPN).

The McNemar test was performed to compare diagnostic ability between systematic biopsy and fusion-targeted biopsy and the Mann–Whitney *U*-test was used to determine any suspicious progression shown by mpMRI during follow-up.

All comparative analyses were bilateral and a 5% significance level ($p < 0.05$) was used as a cut-off for statistically significant differences. The analyses were performed using SPSS v.22.0 (SPSS Inc.).

3 | RESULTS

3.1 | Clinical characteristics of the cohort

A total of 229 patients were included in the study. Further demographic and clinical data of the cohort are listed in Table 1.

The mean follow-up was 49.68 months. Of the total cohort, 134 patients (58.5%) began active treatment, either due to histological progression ($n = 119$, 88.8%), clinical progression ($n = 1$, 0.7%), or patient anxiety ($n = 14$, 10.6%). Five patients (2.1%) died during follow-up, but only one because of cancer.

3.2 | mpMRI at confirmatory biopsy

At confirmatory biopsy, mpMRI provided a clear prediction of reclassification, with 63% versus 37% of patients reclassified in case of a PIRADS score ≥3 versus <3, respectively (Figure 1). When evaluating specifically the value of targeting versus systematic biopsy in this setting, from those 92 (41.4%) patients who had targeted confirmatory biopsies (in one case with suspicious findings on mpMRI and who had undergone only a systematic biopsy), a total of 84.8%

TABLE 1 Clinical characteristics of the cohort.

	***n* = 229**
Age at diagnosis; years	69.02 (±7.73)
Total PSA; ng/mL	6.06 (±2.88)
Free PSA; %	18.6 (±8.52)
PSA density; ng/mL/cc	0.15 (±0.08)
Prostate volume; cc	47.13 (±21.24)
Clinical stage; patients	
T1a	6 (2.6%)
T1c	201 (87.8%)
T2a	22 (9.6%)
Number of patients with a previously negative Bx; patients	53 (±23.14)
mpMRI before 1ª Bx; patients	33 (14.5%)
mpMRI before confirmatory Bx; patients	148 (66.4%)
Median follow-up; months	49,68 (±25.57)
Patients with ≥2 on mpMRI during follow-up; patients	90 (62.94%)
Progression of follow-up; patients	134 (58.5%)
Histological progression	119 (88.8%)
Clinical progression	1 (0.7%)
Anxiety	14 (10.6%)

Abbreviations: Bx, biopsy; mpMRI, multiparametric magnetic resonance; PSA, prostate-specific antigen.

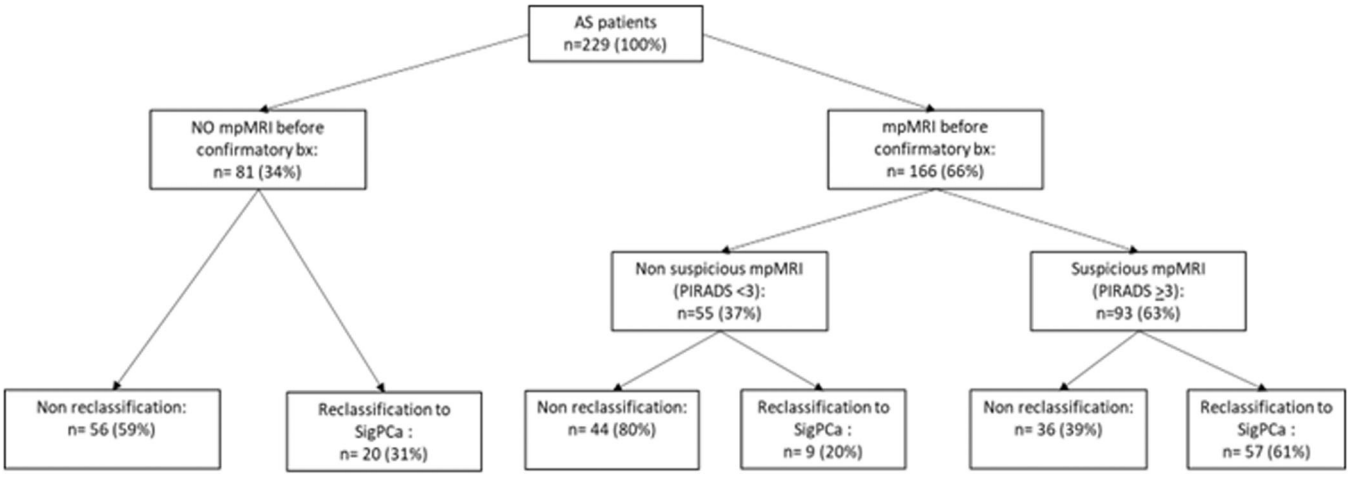

FIGURE 1 Distribution of the reclassification pattern at confirmatory biopsy. As, active surveillance; Bx, biopsy; mpMRI, multiparametric magnetic resonance; SigPCa, significant prostate cancer.

TABLE 2 SigPCa detection ability between systematic biopsy versus targeted biopsy (McNemar test, $p < 0.05$).

	Confirmatory Bx positive for SigCa		
	No	Yes	Total
Systematic bx positive for SigCa			
No	44 (100%)	15 (31.3%)	69 (64.1%)
Yes	0 (0%)	33 (68.8%)	33 (35.9%)
Total	44 (47.8%)	48 (52.2%)	92 (100%)

Abbreviations: Bx, biopsy; SigPCa, significant prostate cancer.

targeted biopsies were diagnostic of PCa (52.2% corresponding to SigPCa).

In 15 patients (31.3% of cases), it was only the fusion biopsy that reclassified the patients as SigPCa ($p < 0.001$) (Table 2).

3.3 | mpMRI during follow-up

During follow-up, 90 patients (62.94%) underwent at least two or more mpMRIs with a median follow-up of 29 (15–49) months. A PIRADS score for baseline mpMRI (before diagnostic or confirmatory biopsy) and the radiological evolution of the index lesions during follow-up are summarized in Table 3.

Progression-free survival was longer in those patients with a non-suspicious mpMRI ($p < 0.05$) due to reclassification to SigPCa of suspicious mpMRI after confirmatory biopsy and subsequent biopsies in the first 12 months of follow-up (Figure 2).

Of 56 patients with non-suspicious baseline mpMRI (PIRADS < 3), 14 patients (25%) had an increased degree of radiological suspicion with an increase in the PSA level in 30.4% of cases. Those patients in whom mpMRI showed progression had a higher detection rate of SigPCa (29%) versus those with no changes on mpMRI (21%).

Similar results were shown with the 14 patients with a PIRADS 3 score on baseline mpMRI; 29% progressed radiologically with a 50% histological progression rate. In this situation, the PSA level increased in 80% of cases. Only 10% (1/10 patients) with a steady or less suspicious mpMRI were diagnosed with SigPCa.

Twenty patients registered a highly suspicious baseline mpMRI (PIRADS ≥ 4); only one who was diagnosed with SigPCa had a radiological progression. Nevertheless, four patients (15%) with a baseline mpMRI and without radiological progression developed a SigPCa. In this situation, the PSA level increased only in the patient with radiological progression.

3.4 | Ability of mpMRI in all AS settings

The overall mpMRI TFN and TFP (pre-biopsy confirmatory and protocol follow-up biopsy) for the detection of PCa was 13% and 44%, respectively. The overall PPV and NPV were 45% and 91%, respectively. Stratified data are shown in Tables 4 and 5.

4 | DISCUSSION

An AS approach is a safe alternative in the management strategy of patients with low-risk PCa, avoiding overtreatment and its secondary effects in patients with a low likelihood of developing a clinically significant and aggressive prostate cancer.[2–5]

Traditionally, AS protocols have been based on a confirmatory biopsy along with PSA determination, DRE, and monitoring biopsies during follow-up.[24]

The European Association of Urology promotes and encourages the use of mpMRI in AS; however, there is still no consensus about the specific role of mpMRI in these protocols. The recent Delphi consensus, through the "Movember"-funded Global Action Project 3

TABLE 3 Radiologic and histologic evolution of lesions detected on baseline mpMRI during follow-up in patients with ≥2 mpMRI.

	Baseline	Decrease	Steady	Increase	Median (months)
PIRADS 2	56 (66%)		42 (75%)	14 (25%)	34 (23–51)
SigPCa	13 (23%)		9 (21%)	4 (29%)	
No SigPCa	43 (77%)		33 (79%)	10 (71%)	
PIRADS 3	14 (16%)	3 (21%)	7 (50%)	4 (29%)	22 (11–47)
SigPCa	3 (21%)		1 (4%)	2 (50%)	
No SigPCa	11 (79%)	3 (100%)	6 (86%)	2 (50%)	
PIRADS 4	19 (21%)	7 (37%)	11 (58%)	1 (5%)	15 (11–42)
SigPCa	4 (21%)	1 (14%)	2 (18%)	1 (100%)	
No SigPCa	15 (79%)	6 (86%)	9 (82%)		
PIRADS 5	1 (1%)	1 (100%)			11 (11–11)
SigPCa	0 (0%)	0 (0%)			
No SigPCa	1 (100%)	1 (100%)			
Total	90	11	60	19	29 (15–49)
SigPCa	20 (22%)	1 (9%)	12 (20%)	7 (37%)	

Abbreviations: mpMRI, multiparametric magnetic resonance imaging; SigPCa, significant prostate cancer.

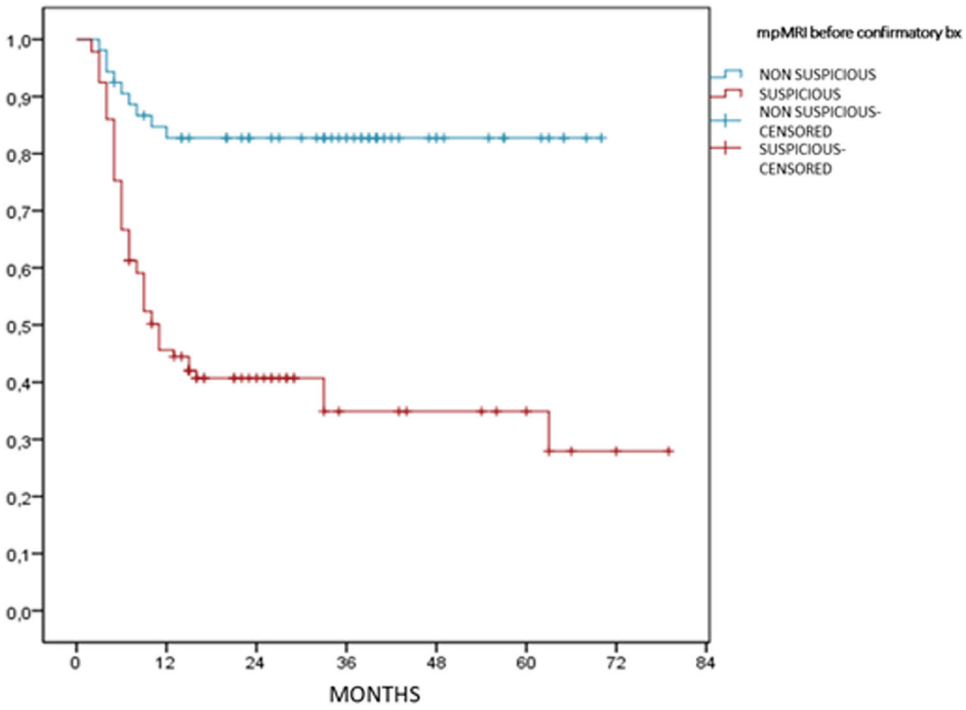

FIGURE 2 Progression-free survival time according to mpMRI suspicion before confirmatory biopsy. mpMRI, multiparametric magnetic resonance imaging. [Color figure can be viewed at wileyonlinelibrary.com]

on Active Surveillance (GAP3), recognized the priority to explore the role of mpMRI during AS.[25]

The introduction of mpMRI before the confirmatory biopsy and, recently, before diagnostic biopsy, has allowed an accurate stratification and better selection of the candidates for AS. This is because mpMRI can detect suspicious lesions subsidiary to a targeted biopsy, consequently achieving an early reclassification/restaging to SigPCa in an important percentage of patients who initially were included in AS protocols.[8–10,26–32] Our results further confirm this hypothesis, with 31.3% of the 58% of cases reclassified to SigPCa being

TABLE 4 Sensitivity and specificity analysis of mpMRI before confirmatory biopsy.

	SigPCa	PCa	Total
Suspicious mpMRI	49	44	93
Non-suspicious mpMRI	5	50	55
Total	54	94	148

Note: S: 49/54 = 0.91, E: 50/94 = 0.53, PPV: 49/93 = 0.53, NPV: 50/55 = 0.91.

Abbreviations: mpMRI, multiparametric magnetic resonance imaging; SigPCa, significant prostate cancer.

TABLE 5 Sensitivity and specificity analysis of the mpMRI before monitoring biopsies performed during follow-up.

	SigPCa	PCa	Total
Suspicious mpMRI	19	38	57
Non-suspicious mpMRI	5	54	59
Total	24	92	116

Note: S: 19/24 = 0.79, E: 54/92 = 0.59, PPV: 19/57 = 0.33, NPV: 54/59 = 0.91.

Abbreviations: mpMRI, multiparametric magnetic resonance imaging; SigPCa, significant prostate cancer.

diagnosed only by the target biopsy in those with suspicious lesions on mpMRI before confirmatory biopsy. The significant number of patients with no mpMRI before confirmatory biopsy in the historical cohort could partly explain the higher rate of reclassification/progression in our cohort.

Of primary interest is to reduce the number of protocol-dictated follow-up biopsies by mpMRI, avoiding discomfort and morbidity for the patient, which are the main reasons that AS protocols are abandoned.[26,27] In fact, in our cohort, up to 10.6% of patients abandoned the AS protocol during follow-up due to the anxiety and discomfort caused by the need to perform repeated biopsies. However, mpMRI data during follow-up have shown heterogeneous results in terms of biopsy avoidance.[12,17,33–37] There are two different interpretations: on the one hand, investigators in the DETECTIVE trial concluded that systematic biopsies during follow-up in patients without suspicious lesions on mpMRI could be avoided due to the low detection of SigPCa.[12,17] This was further supported by Giganti et al.[37] and Amin et al.,[33] in the MRIAS trial, which recommended induced biopsy only in those situations in which there was radiological progression or an increase in PSAD. On the other hand, other groups, such as Hettiarachchi et al., concluded that mpMRI cannot be considered sufficiently accurate to detect disease progression on its own, and, therefore, cannot yet replace prostate biopsy, due to its variability and non-perfect NPV.[17,34–38] In our cohort, despite strict VA criteria without the inclusion of favorable intermediate-risk PCa, mpMRI reached a high NPV for any ISUP ≥ 2, not only in confirmatory biopsy, but also in follow-up biopsies (NPV = 0.91).

One concern discussed recently in the literature is the need for a new risk-group categorization, which could define new low-risk groups as those patients who demonstrate an mpMRI with small ISUP 2 lesions but negative systematic biopsy, who would probably not experience a survival benefit from the treatment.[39]

Another issue with mpMRI is the variability in its evaluation during AS follow-up. This is also one of the limitations of our cohort with no specific mpMRI evaluation criteria (i.e., PRECISE). With the goal of data homogenization and to establish criteria to resolve these issues, in 2017 the PRECISE recommendations for the description of lesions identified on mpMRI were published, defining new categories of disease monitoring.[18,37,40] Several groups have analyzed the correlation between radiological progression and biopsy results, observing that radiological progression was significantly higher in those patients who presented with a suspicious or indeterminant baseline mpMRI, establishing that baseline mpMRI was an independent prognostic factor for disease-free progression.[11,41–43] This observation has not been corroborated in our study; one possible explanation, apart from the possible bias in the retrospective design and no PRECISE criteria, could be the high rate of reclassification after a suspicious baseline mpMRI confirmatory biopsy which resulted in a shorter AS follow-up than those patients with a normal baseline mpMRI who continued longer in AS.

Our work reaffirms the usefulness of mpMRI in AS protocols not only in confirmatory biopsy and patient selection, but also to improve follow-up because of a high NPV, and as a prediction radiological tool depending on the follow-up mpMRI risk monitoring. However, several limitations should be considered: (a) the retrospective nature of the study and the fact that only very low-risk patients (ISUP 1) were included; (b) VA protocols have changed during the last few years, causing heterogeneous data that could have had an impact on the results of this analysis. Fundamentally, these changes could be associated with the introduction of mpMRI before diagnostic Bx, before confirmatory Bx, and during follow-up; (c) the data were not re-evaluated after homogenizing the criteria for image interpretation (PIRADS) and pathological anatomy, but adhered to what existed in clinical practice at the corresponding time, which could have led to biases in non-contemporaneous comparisons; and, finally, (d) the evolution of the interpretation of suspicious images (mpMRI) did not adhere to the PRECISE guidelines until last year, introducing a possible bias in the interpretation.

5 | CONCLUSIONS

mpMRI before confirmatory biopsy has an essential role in those patients who are candidates for AS, allowing an optimal stratification because of the performance of targeted biopsies by image fusion in those cases with a suspicious lesion. In addition, mpMRI provides criteria with which to establish less stringent surveillance protocols in patients at low-risk of progression and non-suspicious mpMRI.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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