**Is MRI ready to replace biopsy during active surveillance?**

**Abstract**
Active surveillance (AS) is a conservative management option recommended for patients diagnosed with low-risk prostate cancer (PCa) and selected cases with intermediate-risk PCa. The adoption of prostate MRI in the primary diagnostic setting has sparked interest in its application during AS. This review aims to examine the role and performance of multiparametric MRI (mpMRI) across the entire AS pathway, from initial stratification to follow-up, also relative to the utilization of the Prostate Cancer Radiological Estimation of Change in Sequential Evaluation (PRECISE) criteria. Given the high negative predictive value of mpMRI in detecting clinically significant PCa (csPCa), robust evidence supports its use in patient selection and risk stratification at the time of diagnosis or confirmatory biopsy. However, conflicting results have been observed when using MRI in evaluating disease progression during follow-up. Key areas requiring clarification include addressing the clinical significance of MRI-negative csPCa, optimizing MRI quality, determining the role of biparametric MRI (bpMRI) or mpMRI protocols, and integrating artificial intelligence (AI) for improved performance.
**Clinical relevance statement**
MRI plays an essential role in the selection, stratification, and follow up of patients in active surveillance (AS) for prostate cancer. However, owing to existing limitations, it cannot fully replace biopsies in the context of AS.
**Key Points**
- *Multiparametric MRI (mpMRI) has become a crucial tool in active surveillance (AS) for prostate cancer (PCa)*.
- *Conflicting results have been observed regarding multiparametric MRI efficacy in assessing disease progression*.
- *Standardizing MRI-guided protocols will be critical in addressing current limitations in active surveillance for prostate cancer*.

## Introduction

Active surveillance (AS) is a management option recommended for patients diagnosed with low-risk prostate cancer (PCa) and selected cases with intermediate-risk PCa. The primary goal of AS is to mitigate the risk of overtreatment and procedure-related complications while ensuring timely intervention in case of disease progression, thereby preserving the opportunity for curative treatment [1].

Currently, there is considerable heterogeneity in the inclusion criteria and monitoring procedures of AS (Table 1). Typical AS protocols require an early confirmatory biopsy within one year after diagnosis, preferably under magnetic resonance imaging (MRI) guidance, followed by sequential biopsies every two to three years [1,2,3]. In recent years, the adoption of prostate MRI in the primary diagnostic setting has sparked interest in its application during AS [4].

Given the high negative predictive value (NPV) of a non-suspicious MRI (PI-RADS/Likert scores 1–2) for clinically significant PCa (csPCa), the notion of patients with negative or

stable multiparametric MRI (mpMRI) avoiding scheduled biopsies is appealing to both clinicians and patients [5].

To date, AS protocols worldwide and international guidelines have incorporated MRI either during initial stratification or as part of follow-up procedures [1, 2, 6,7,8,9]. Nonetheless, the oncologic safety of avoiding biopsies in patients with stable or negative mpMRI results during AS remains a subject of controversy [3, 10], and further studies are necessary to refine the implementation of the MRI-driven approach in clinical practice. Moreover, the increasing global utilization of MRI in AS underscores the need for a standardized approach to performing, interpreting, and scoring MRI in this context.

Since the established PI-RADS scoring system does not consider temporal changes in prostate MRI findings over time [11], the Prostate Cancer Radiological Estimation of Change in Sequential Evaluation (PRECISE) recommendations were first proposed in 2016, specifically aimed at standardizing the reporting of serial MRIs during AS [12], and have been recently updated to version 2 [13].

In light of the complexities of AS and of MRI utilization in this context, we aim to examine the role and performance of mpMRI across the entire AS pathway, from initial stratification to follow-up, also relative to the utilization of the PRECISE criteria.

## Role of MRI for active surveillance

### At the time of diagnosis or confirmatory biopsy

The integration of mpMRI into the diagnostic pathway of PCa significantly reduces the need for unnecessary biopsies, while simultaneously increasing the detection rate of csPCa and decreasing that of insignificant PCa [14]. Moreover, it diminishes the risk of Grade Group (GG) upgrading at radical prostatectomy [15]. Incorporating mpMRI with targeted biopsies at the initiation of AS could ensure optimal sampling and minimize subsequent reclassification.

A substantial body of evidence already supports the notion that an early MRI in AS improves risk stratification [16,17,18]. In the study by Stavrinides et al on an AS cohort with over 3800 person-years [19], the primary factor driving treatment discontinuation aside from secondary Gleason pattern 4 at baseline was the visibility of MRI findings at baseline, specifically Likert scores of 4–5. Interestingly, MRI-visible lesions with GG1 demonstrated outcomes comparable to those of non-visible GG2 disease. This finding suggests that MRI-visible lesions may follow a distinct radiological, pathological, and clinical course.

The randomized controlled ASIST trial evaluated whether the outcomes on confirmatory biopsy one year after the initiation AS with GG1 differed between patients who underwent a 12-core confirmatory biopsy vs mpMRI-targeted biopsy (Table 2) [20]. Initially, a significant difference in the prevalence of GG ≥ 2 at confirmatory biopsy among the randomization groups was not observed. However, the findings after two years revealed that 10% of patients in the MRI group exhibited GG ≥ 2 at follow-up

biopsy after confirmatory biopsy, compared to 23% in the systematic biopsy-only group [17]. The disparity between the initial and updated results may be attributed to the better identification of csPCa through MRI-targeted biopsy, leading to reduced rates of AS failure and grade progression over a longer follow-up period. Overall, these findings underscore the importance of an MRI-informed confirmatory biopsy for enhanced risk stratification, ultimately leading to a 50% reduction in the risk of reclassification in the long term. Figure 1 illustrates an example highlighting the importance of MRI-targeted biopsy.

Efforts have also focused on determining whether systematic biopsies can be omitted when MRI shows suspicious lesions. Recabal et al demonstrated that avoiding surveillance biopsy in patients with no visible MRI lesions would result in missing GG ≥ 2 PCa in 11% of cases, while avoiding systematic biopsy in those with visible MRI lesions would miss csPCa in 13% of cases [21]. These conclusions were further supported by a meta-analysis where Schoots et al reported that MRI-targeted confirmatory biopsies upgraded an additional 7% of patients compared to systematic biopsies [16]. Therefore, most guidelines recommend performing both MRI-targeted and systematic biopsies at the time of the first confirmatory biopsy in AS [1]. Importantly, these findings are derived from studies where MRI-targeted confirmatory biopsies were conducted in patients enrolled in AS with a 12-core systematic biopsy.

Endeavours have been made to understand whether patients who are diagnosed with upfront MRI can delay or avoid their follow-up or confirmatory biopsies.

The MRIAS study investigated whether an early confirmatory biopsy could be avoided in favor of yearly MRIs followed by a mandatory three-year biopsy, as shown in Table 2 [18]. Upon completion of the 3-year biopsy, 14% patients with persistently negative MRIs (PI-RADS 1-2) had csPCa, resulting in a NPV for a persistently negative MRI of 86% (95% CI 81–90%). Biopsy was deferred for three years in 71% of patients with negative MRI and stable PSA, potentially leading to a delay in the diagnosis of csPCa in up to 8% of cases. Of note, 73% of patients diagnosed with csPCa despite a non-suspicious MRI exhibited organ-confined GG2 disease upon radical prostatectomy, suggesting that csPCa missed by MRI may be less aggressive than MRI-visible csPCa. Therefore, in patients diagnosed with an upfront MRI, confirmatory biopsy could be delayed rather than avoided [1].

At the time of follow-up (serial MRI)
Several studies aimed to determine whether a favorable MRI—either one that remains non-suspicious over time or one that shows no signs of progression—can be used alone to avoid surveillance biopsies. In a recent systematic review and metanalysis, a NPV between 80 and 90% has been reported, indicating that approximately 10 to 20% of patients with a favorable MRI harbour csPCa that would be missed if a scheduled biopsy is omitted [22]. Additionally, MRI progression (defined as either an increase in the suspicion score, an increase in the size of the index lesion, or evidence of extraprostatic extensions) has a very low positive predictive value (PPV) [22]. Based on a prevalence of pathological progression between 20 and 30%, the PPV of an MRI

showing progression ranged from 37 to 50%. This suggests that over half of the patients with MRI progression during AS do not experience pathological upgrading.

In all, a negative MRI demonstrates superior performance compared to a positive (or progressive) MRI in predicting biopsy results. Furthermore, it must be noted that most evidence regarding the utility of sequential MRIs in AS is derived from studies with relatively short follow-ups (< 5 years), focusing on early biopsy outcomes [22]. Nevertheless, outcomes from a large single-center cohort demonstrated that MRI-driven AS is safe and yields comparable results to cohorts of patients undergoing AS with scheduled serial biopsies [19]. This holds particular significance, especially in light of the decreased compliance rates observed for repeat biopsies over time [23], potentially undermining the value of a mandated biopsy protocol.

The recent ProtecT trial demonstrated that even in patients diagnosed without MRI and monitored predominantly using prostate specific antigen (PSA), the risk of metastasis was < 10% at 15 years [24]. Furthermore, the risk of non-PCa-related death can be significant in AS patients. Consequently, one could argue that current approaches, including the MRI diagnostic pathway, risk calculators, biomarkers, and follow-up MRI with scheduled biopsies, may be overly aggressive. However, until less stringent approaches are proven effective, they should be reserved for expert centers, and any potential de-intensification should be guided by clinicopathologic cancer factors, increasing age, and comorbidities [25]. The results from a recently funded randomized controlled trial in the UK (NIHR152027) will contribute to understanding the effectiveness and compliance of MRI-driven versus conventional AS protocols [26].

PRECISE vs non-PRECISE

The PRECISE recommendations have been introduced to standardize the reporting of sequential MRIs in AS [12]. Utilizing a five-point scale, PRECISE describes radiological changes relative to previous surveillance MRIs: a PRECISE score of 1 indicates resolution of previously suspicious areas; a score of 2 implies regression of areas that remain suspicious; a score of 3 indicates stability (Figs. 2, 3); scores 4 and 5 (Figs. 4–6) indicate progression. To date, there are no large prospective studies validating this reporting tool, with many centers still relying on institution-specific criteria to define radiological changes in AS [18, 22].

The recent PROMM-AS is the sole prospective study to evaluate the PPV and NPV of the PRECISE scores through a scheduled two-year biopsy in patients with GG1 or GG2 PCa who were enrolled in AS following an equivocal or suspicious MRI [27]. Its primary objective was to assess whether an MRI-guided early AS strategy would result in a low progression rate on a scheduled two-year biopsy, but it did not meet this endpoint. Nonetheless, in GG1, the NPV for PRECISE scores 1–3 (indicating radiological regression or stability) was 88%, albeit based on a very limited number of events (Table 2).

The majority of the evidence of the PRECISE recommendations in predicting csPCa stems from retrospective studies (Table 3) and was summarized in a recent meta-analysis [22]. O'Connor et al assessed 391 patients on AS whose MRIs were evaluated using the PRECISE recommendations, reporting a NPV of 76% (95% CI 71–81%) for

PRECISE scores 1–3 in predicting progression from GG 1 to GG ≥ 2 [28]. Giganti et al demonstrated that the PRECISE 4 encompasses a heterogeneous group [29]. Specifically, in a study where surveillance biopsies were conducted solely in the presence of signs of radiological progression, individuals progressing from a non-suspicious scan (e.g., from PI-RADS/Likert 1–2 to PI-RADS/Likert 4–5) exhibited a lower risk of higher-grade cancer on biopsy (26%) compared to those with an increase in size or conspicuity of a suspicious lesion (86%).

In a recent meta-analysis, Rajwa et al reported no significant differences in the positive or negative predictive values for pathological progression between the PRECISE scores and institution-specific criteria [22]. Specifically, the PPV for PRECISE 4–5 was 50% (95% CI 31–70%) and 49% (95% CI 34–64%) for institution-specific criteria, respectively. The NPVs were 88% (95% CI 81–94%) for PRECISE and 83% (95% CI 77–88%) for institution-specific criteria, respectively. All studies included in the meta-analysis assessed progression at different AS time points, requiring careful interpretation of the derived performance metrics due to inherent heterogeneity. Moreover, centers that did not adopt the PRECISE recommendations were predominantly high-volume institutions.

One of the primary drawbacks of any scoring system for monitoring MRI changes during AS is that the majority of patients show no significant changes over time, with some authors calling into question the utility of evaluating overall changes rather than the PI-RADS/Likert score on a given scan [30]. In addition, studies examining the NPV of stable MRIs (including those using the PRECISE recommendations) encounter challenges related to ascertainment bias. This bias arises when the decision to conduct a surveillance biopsy depends on MRI findings, which may artificially inflate the apparent NPV of the test [19].

In particular, the original PRECISE recommendations face several limitations, notably the absence of guidance on tumor size measurement methods or size progression thresholds. Moreover, there is ambiguity regarding whether the calculation of the PRECISE score should be based on baseline MRI or the most recent imaging, and how to approach stable MRI-visible versus MRI-invisible disease. To tackle these contentious issues, version 2 of the PRECISE recommendations has been recently developed by an expert consensus panel and awaits further validation [13].

## Discussion

MRI has undeniably emerged as an indispensable tool in the contemporary era of AS. Its exceptional diagnostic performance, notably its high NPV, plays a pivotal role in various aspects of AS, including guiding targeted biopsies, selecting optimal candidates, and identifying progression. Evidence already supports its use in patient selection and risk stratification, while suboptimal results have been observed when using MRI in evaluating disease progression during follow-up,

Hence, the question arises: “Is MRI ready to replace biopsy during AS?”.

Our response, to date, is a cautious “no”. Despite all the strengths of MRI, evidence suggests that it cannot yet fully replace biopsy during AS.

One issue that needs to be clarified is the clinical significance of missed csPCa by MRI. While already established that the prevalence of csPCa is low in patients with a negative MRI, the true significance of cancers detected in this setting is not clear [24, 31, 32]. There is increasing evidence that the oncologic risk (e.g., biochemical recurrence and cancer-specific mortality) is substantially lower in csPCa in patients with a negative compared with a positive MRI [33]. In this regard, “false-negative” MRI for csPCa at confirmatory biopsy or during AS may not be as critical as initially thought.

Additional important efforts are needed to maximize the role MRI plays in AS today and to even potentially replace biopsy in the future.

First, we need to ensure high quality of MRI to achieve the highest possible diagnostic performance for detecting, characterizing, and determining progression. It has been shown that poor image quality negatively affects its performance and systematic measures have been proven to improve image quality at the global level [34,35,36]. The Prostate Imaging Quality (PI-QUAL) score (and its future iterations) or other standardized methods of assessing MRI quality are gaining interest and will be instrumental in achieving this goal [37].

Second, the use of MRI without intravenous contrast medium in the setting of AS needs to be further investigated. While MRI without intravenous contrast medium has shown potentially equivalent performance to multiparametric MRI for the detection of csPCa, its role in AS is yet to be established [38,39,40].

Finally, standardization of how MRI is acquired and interpreted for AS needs to be established. Although the current evidence does not show the superiority of standardized approaches (i.e., PRECISE) when compared with institution-specific scales, lessons can be learned from PI-RADS replacing institution-specific scales as a global standard because of this standardization [41].

Continuous effort is needed to homogenize imaging approaches across institutions to facilitate multi-institutional research and ultimately better patient outcomes [13, 42]. In this context, radiomics and artificial intelligence (AI) might play a role in addressing several challenges associated with MRI in AS, including standardizing serial MRI assessments, evaluating the progression of MRI-visible lesions and mitigating interreader variability in MRI interpretation, particularly among non-expert readers [43, 44].

In conclusion, MRI is not yet ready to fully replace biopsies during AS. However, MRI plays an essential role in providing the most value together with clinical and pathological information, especially in the selection and stratification of patients in AS. As we move forward, it is imperative to address key issues such as the clinical significance of MRI-negative csPCa, MRI quality, the use of MRI without intravenous contrast medium or mpMRI, and the integration of AI. Tackling these challenges will be essential in expanding the role of MRI in AS and potentially replacing biopsies in the future.

**Abbreviations**

***AI:***
Artificial intelligence

***AS:***
Active surveillance

***csPCa:***
Clinically significant prostate cancer

***GG:***
Grade group

***mpMRI:***
Multiparametric MRI

***MRI:***
Magnetic resonance imaging

***PCa:***
Prostate cancer

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