

Confirmatory Magnetic Resonance Imaging with or without Biopsy Impacts Decision Making in Newly Diagnosed Favorable Risk Prostate Cancer

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Purpose: We investigated how magnetic resonance imaging and post-magnetic resonance imaging biopsy impact decision making in men considering active surveillance.

Materials and Methods: We reviewed the records of men in the Michigan Urological Surgery Improvement Collaborative with newly diagnosed favorable risk prostate cancer. Following diagnostic biopsy the men were classified into 3 groups, including group 1—no magnetic resonance imaging, group 2—magnetic resonance imaging only and group 3—magnetic resonance imaging/post-magnetic resonance imaging biopsy. For the purposes of counseling and shared decision making magnetic resonance imaging results were deemed reassuring (PI-RADS™ [Prostate Imaging Reporting and Data System] 3 or less) or nonreassuring (PI-RADS 4 or greater). Similarly, if the diagnostic biopsy was GG (Grade Group) 1, post-magnetic resonance imaging biopsy results were deemed nonreassuring if there was any amount of GG 2 or greater. If the diagnostic biopsy was GG 2, post-magnetic resonance imaging biopsy results were deemed nonreassuring if more than 3 cores were GG 2, or there was more than 50% GG 2 in any individual core or any volume of GG 3 or greater.

Results: Of 1,461 men with favorable risk prostate cancer 1,223 (84%) did not undergo magnetic resonance imaging, 157 (11%) underwent magnetic resonance imaging alone and 81 (6%) underwent magnetic resonance imaging and post-magnetic resonance imaging biopsy. Of the men who underwent magnetic resonance imaging alone more with reassuring findings elected active surveillance than men with nonreassuring or magnetic resonance imaging findings (74% vs 35% and 42%, respectively). The highest rate of active surveillance was noted in men with reassuring post-magnetic resonance imaging biopsy regardless of whether magnetic resonance imaging was reassuring or nonreassuring (93% and 96%, respectively).

Conclusions: Magnetic resonance imaging and post-magnetic resonance imaging biopsy drive decision making in men with newly diagnosed, favorable risk prostate

Abbreviations and Acronyms

AS = active surveillance
Bx = biopsy
dBx = diagnostic Bx
FRPC = favorable risk prostate cancer
GG = Grade Group
MRI = magnetic resonance imaging
MUSIC = Michigan Urological Surgery Improvement Collaborative
nonRA = nonreassuring
PI-RADS™ = Prostate Imaging and Reporting Data System
pMRI = post-MRI
RA = reassuring

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cancer. Post-magnetic resonance imaging biopsy is a stronger driver of decision making than magnetic resonance imaging alone. This was demonstrated by the more than 90% of men with reassuring post-magnetic resonance imaging biopsies who elected active surveillance regardless of magnetic resonance imaging results.

Key Words: prostatic neoplasms, magnetic resonance imaging, clinical decision-making, watchful waiting, risk

THE last 2 decades have seen dramatic changes in the management of prostate cancer.¹ Concerns surrounding the over diagnosis and overtreatment of patients at low risk for metastasis and death from prostate cancer have led to the adoption of AS. Critical to any AS protocol is assessment of the disease burden (Bx grade and volume), which provides a basis for risk stratification. Upgrading on repeat and surveillance Bx remains common among AS cohorts.^{2,3}

To help improve shared decision making, MUSIC created a Roadmap for FRPC in which 2 separate phases are conceptualized, including 1) the consideration phase and 2) the surveillance phase.^{4,5} The consideration phase, which encompasses up to the first 6 months after the diagnosis of FRPC, is a time during which 1 or more confirmatory tests, including MRI with or without pMRI Bx or tumor genomics, are performed to optimize risk stratification and improve counseling. Results of the confirmatory tests must then be discussed with the patient during a new round of shared decision making. After a patient has elected AS, he exits the consideration phase and enters the surveillance phase, during which long-term disease monitoring ensues.

Multiple groups have reported that multiparametric MRI with targeted Bx of suspicious lesions is useful for diagnosing prostate cancer and assessing tumor burden, focusing on correlation of the PI-RADS™ score with targeted Bx and radical prostatectomy pathology.^{6–12} Little is known about how MRI with and without Bx influences clinical decision making. We investigated the impact of prostate MRI with and without targeted pMRI Bx in the shared decision making process shortly after the diagnosis of FRPC.

MATERIALS AND METHODS

MUSIC is a physician led, statewide quality improvement collaborative. Approximately 90% of the urologists in Michigan participate in MUSIC, including physicians from private practice, and academic and hospital employed groups. Data are entered in the web based registry at the time of prostate Bx. The registry is maintained by trained data abstractors who review the primary medical record for pertinent clinical and laboratory parameters at fixed intervals. The registry is regularly audited for accuracy. Importantly the registry includes a check box for affirmative selection of AS. Approval to participate in MUSIC was obtained from the Institutional Review Board at each practice and institution. This study was deemed exempt by the Wayne State University Institutional Review Board.

To assess how MRI and pMRI Bx affect decision making we performed a retrospective cohort study of men with newly diagnosed FRPC who were entered in the registry from June 2016 to April 2017. MUSIC defines FRPC as any volume of GG 1 or low volume GG 2 (3 or fewer positive cores and 50% or less GG 2 involvement of any individual core). In this study pMRI Bx was defined as Bx obtained after MRI and within 1 year of dBx with or without fusion technology. Men were classified into 3 groups, including group 1—no MRI, group 2—MRI alone and group 3—MRI/pMRI Bx. Men in whom a genomics test was done on the dBx or the pMRI Bx were excluded from study.

For the purposes of counseling and shared decision making the results of the MRI and the pMRI Bx were deemed RA or nonRA. Test results were deemed nonRA if they indicated higher risk disease than the dBx, implying the need for more intense counseling. For MRI a nonRA result was a PI-RADS version 2 score of 4 or 5.¹³ If the dBx result was GG 1, a pMRI Bx result of greater than GG 1 was deemed nonRA. If the dBx result was low volume GG 2, a pMRI Bx result of more than 3 GG 2 cores, more than 50% GG 2 involvement of any core or the presence of GG 3 or greater was deemed nonRA.

The primary outcome was the proportion of patients who elected AS defined as 1) affirmative selection of AS in the registry as the primary management strategy and 2) no curative treatment within 1 year of the diagnosis date. If the patient initially considered AS (obtained confirmatory testing) but received treatment within 1 year of diagnosis (eg due to a nonRA confirmatory test result or any other reason), he was not considered to have elected AS. The secondary outcome was time in months to any definitive treatment after the dBx.

Clinical and demographic characteristics were compared in patients without MRI, with MRI alone or with MRI/pMRI Bx using the chi-square test for categorical measures and the Wilcoxon rank sum test for continuous measures. The proportion of patients who elected AS was summarized and compared using the chi-square test. We applied the Kaplan-Meier method to calculate the treatment-free probability and the log rank test to compare treatment free survival across subgroups. All analyses were performed with SAS® 9.4 and statistical significance was considered at $p < 0.05$.

RESULTS

From June 2016 to April 2017 a total of 1,461 men with newly diagnosed FRPC from 26 MUSIC practices met study inclusion criteria. During the consideration phase MRI alone was done in 157 of these men (11%) and pMRI Bx was done in 81 (6%). Median age of the cohort was 65 years (IQR 59.3–69.7) and median followup was 20 months (IQR 17.4–22.7).

Table 1. Patient clinical and demographic characteristics

	Overall	No MRI	MRI Only	MRI/Post-MRI Biopsy	p Value
No. pts	1,461	1,223	157	81	—
Median age (IQR)	64.5 (59.3–69.7)	64.8 (59.4–69.8)	63.2 (58.6–68.2)	64.0 (58.1–69.0)	0.078
Median kg/m ² body mass index (IQR)	28.2 (25.7–31.6)	28.2 (25.7–31.6)	28.7 (25.8–31.9)	28.2 (25.5–31.4)	0.684
Median ng/ml prostate specific antigen at diagnosis (IQR)	5.5 (4.3–7.5)	5.5 (4.3–7.5)	5.2 (4.1–7.4)	5.3 (4.6–7.1)	0.389
No. diagnostic Bx Gleason score (%):					
3 + 3	1,105 (75.6)	909 (74.3)	128 (81.5)	68 (84.0)	0.028
3 + 4	356 (24.4)	314 (25.7)	29 (18.5)	13 (16.0)	
No. race (%):					
Caucasian	1,104 (84.3)	912 (83.7)	126 (86.3)	66 (89.2)	0.650
African American	163 (12.5)	141 (12.9)	15 (10.3)	7 (9.5)	
Other	42 (3.2)	36 (3.3)	5 (3.4)	1 (1.4)	
No. clinical T stage (%):					
T1c or less	1,258 (86.8)	1,051 (86.6)	136 (87.7)	71 (88.8)	0.803
T2a or greater	191 (13.2)	163 (13.4)	19 (12.3)	9 (11.3)	
No. insurance type (%):					
Private	828 (57.9)	674 (56.4)	100 (64.1)	54 (67.5)	0.112
Public	590 (41.2)	510 (42.7)	54 (34.6)	26 (32.5)	
None	13 (0.9)	11 (0.9)	2 (1.3)	—	
No. Charlson comorbidity index (%):					
0	1,068 (73.2)	890 (72.8)	116 (74.4)	62 (76.5)	0.879
1	238 (16.3)	203 (16.6)	25 (16.0)	10 (12.3)	
2 or Greater	154 (10.5)	130 (10.6)	15 (9.6)	9 (11.1)	
No. prostate Ca family history (%):					
Yes	463 (34.1)	378 (33.4)	55 (37.2)	30 (37.5)	0.532
No	896 (65.9)	753 (66.6)	93 (62.8)	50 (62.5)	

Clinical and demographic features were similar in patients without MRI, with MRI alone and with MRI/pMRI Bx (table 1). Median time from dBx to MRI was 2.5 months (IQR 1.4–3.6) and median time from dBx to pMRI Bx was 5.4 months (IQR 3.7–7.5).

Overall 46% of the men elected AS. Regardless of results, significantly more men with pMRI Bx chose AS than men with MRI alone or men without MRI (74% vs 61% and 42%, respectively) (fig. 1). These data show that ordering MRI or performing pMRI Bx was associated with more men electing AS.

Focusing on the 157 men with MRI alone, in 105 the MRI was RA and in 52 it was nonRA (table 2 and fig. 2, A). Not surprisingly the proportion of men with RA MRI who chose AS was significantly higher than that of men with nonRA MRI (74% vs 35%, p <0.001).

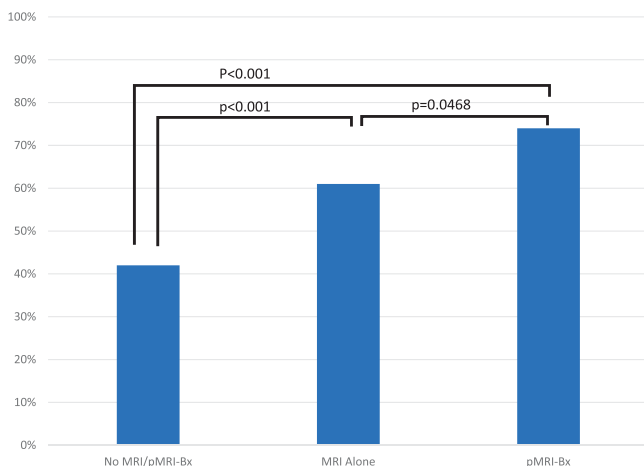


Figure 1. Patients who elected AS regardless of test results

or men without MRI (74% vs 42%, p <0.001). Notably 34 men (65%) with nonRA MRI proceeded to curative therapy without undergoing pMRI Bx. In this group of patients median prostate specific antigen was similar to that of the cohort median (5.8 and 5.5 ng/ml, respectively). However, GG 2 was found on diagnostic Bx in 41% of these patients compared to 24% of the entire cohort (supplementary table, <https://www.jurology.com/>).

Of the 81 men with MRI/pMRI Bx the MRI results were RA and nonRA in 32 (40%) and 49 (60%), respectively (table 2). A median of 12 (IQR 12–16) and 16 cores (IQR 15–18) were obtained in men with

Table 2. Patients who elected active surveillance according to MRI and post-MRI biopsy results with PI-RADS 3 considered reassuring and nonreassuring MRI results

Group Results	No. Active Surveillance/Total No. (%)
<i>PI-RADS 3 considered reassuring MRI result</i>	
Control	518/1,223 (42.4)
MRI alone:	96/157
MRI reassuring	78/105 (74.3)
MRI not reassuring	18/52 (34.6)
MRI + biopsy:	60/81
MRI + biopsy reassuring	26/28 (92.9)
MRI reassuring, biopsy not reassuring	2/4 (50.0)
MRI not reassuring	25/26 (96.2)
MRI + biopsy not reassuring	7/23 (30.4)
<i>PI-RADS 3 considered nonreassuring MRI result</i>	
MRI alone:	96/157
MRI reassuring	65/83 (78.3)
MRI not reassuring	31/74 (41.9)
MRI + post-MRI biopsy:	60/81
MRI + biopsy reassuring	15/15 (100)
MRI reassuring, biopsy not reassuring	2/3 (67)
MRI not reassuring, biopsy reassuring	36/39 (92.3)
MRI reassuring, biopsy not reassuring	7/24 (29.2)

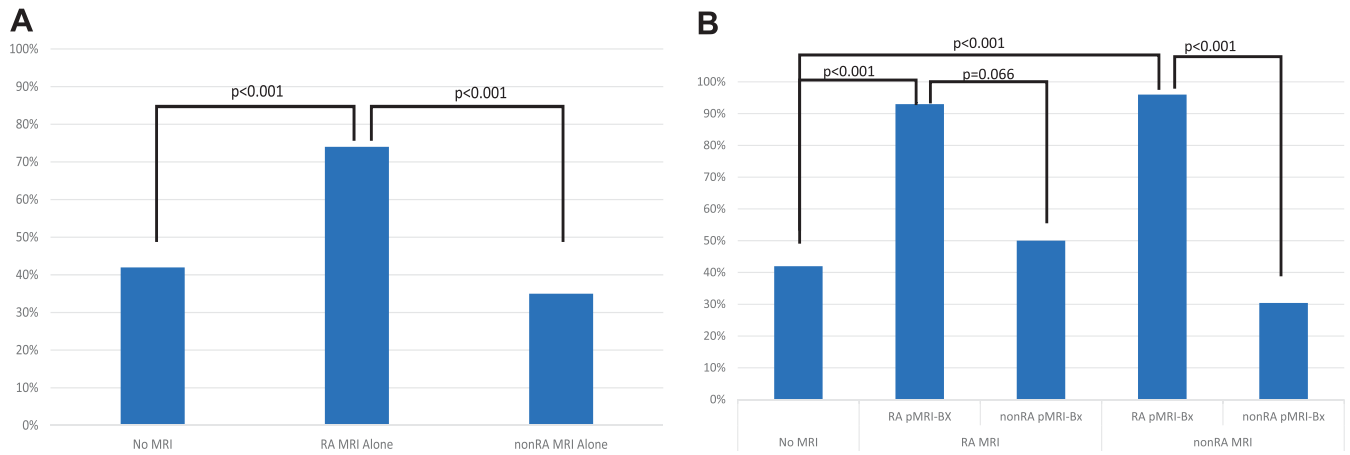


Figure 2. A, patients with MRI alone who elected AS based on RA or nonRA MRI results. B, patients with pMRI Bx who elected AS based on MRI and pMRI Bx results.

RA and nonRA MRI, respectively. Of the 32 men with RA MRI the pMRI Bx results were RA and nonRA in 88% and 12%, respectively. More men with RA MRI and RA pMRI Bx elected AS than men with RA MRI and nonRA pMRI Bx (93% vs 50%, $p = 0.066$) or men without MRI (93% vs 42%, $p < 0.001$, fig. 2, B). Only 2 of the 4 men with nonRA pMRI Bx following RA MRI had GG 3 disease and no patient had GG 4 or 5.

The pMRI Bx results were RA and nonRA in 53% and 47% of the 49 men with nonRA MRI, respectively. MRI ability to predict a nonRA pMRI Bx had 85% sensitivity, 52% specificity, and 47% and 88% positive and negative predictive values, respectively. Of men with nonRA MRI a higher proportion with RA pMRI Bx elected AS than men with nonRA pMRI Bx (96% vs 30%, $p < 0.001$) or men without MRI (96% vs 42%, $p < 0.001$, fig. 2, B).

On secondary analysis we classified PI-RADS 3 lesions as nonRA, which demonstrated a similar trend in the management of RA and nonRA results (table 2). Of the 14 men with PI-RADS 3 lesions who underwent pMRI Bx 13 had reassuring Bx results and there was no GG 3, 4 or 5.

Kaplan-Meier curves of treatment-free survival were constructed for patients with MRI alone and patients with MRI/pMRI Bx. The estimated 12-month treatment-free probability in men with RA MRI alone and nonRA MRI alone was 78% and 38%, respectively, compared to 50% in men without MRI ($p < 0.001$, fig. 3, A). The estimated 12-month treatment-free probability was 96% when the 2 tests were RA, 96% when MRI was nonRA but pMRI Bx was RA and 35% when each test was nonRA ($p < 0.001$, fig. 3, B).

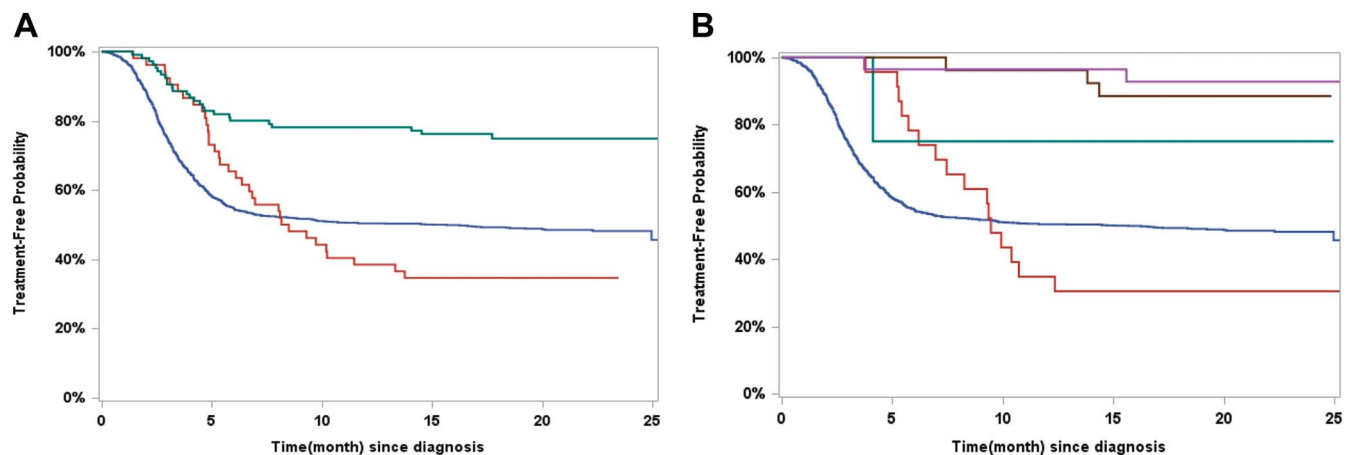


Figure 3. Kaplan-Meier curves of treatment-free probability. A, patients with and without (blue curve) MRI alone. Red curve represents nonRA MRI. Green curve represents RA MRI. B, patients with MRI and pMRI Bx and patients with no MRI (blue curve). Green curve represents RA MRI and nonRA Bx. Purple curve represents RA MRI and RA Bx. Red curve represents nonRA MRI and nonRA Bx. Brown curve represents nonRA MRI and RA Bx.

DISCUSSION

The ability of multiparametric prostate MRI and targeted Bx to detect clinically significant prostate cancer has led to its application as a confirmatory test in newly diagnosed patients with favorable risk prostate cancer.^{14,15} To our knowledge what remains unknown is how reassuring and nonreassuring MRI results alone or combined with additional biopsies influence decision making in men considering active surveillance.

In our study we noted that almost all men with RA pMRI Bx elected AS regardless of whether MRI was RA or nonRA. These data suggest that RA pMRI Bx has the most profound effect on decision making. We also found that the mere performance of a test was associated with the choice of AS. Regardless of results, pMRI Bx yielded the highest percent of men who chose AS, followed by MRI alone and then no MRI.

This study helps answer important questions regarding MRI and pMRI Bx. What drives shared decision making when MRI and pMRI Bx results are discordant? Does the RA pMRI Bx result truly reassure the patient and the urologist or does a PI-RADS 4/5 lesion cloud decision making and overshadow RA pMRI Bx? From our data we infer that 1) the pMRI Bx result drives the shared decision making process more than the MRI result alone and 2) there appears to be some impact of the pMRI Bx on decision making even in the face of RA MRI, which is evident due to the increase in the proportion of men who elected AS with RA pMRI Bx compared with RA MRI alone (93% vs 74%).

Only half of the patients with PI-RADS 4 or 5 lesions had a nonRA pMRI Bx result. While this is consistent with findings in previously reported, large pMRI cohorts,^{12,14,16,17} it is concerning that more than a third of the patients with MRI alone chose curative treatment without undergoing pMRI Bx. Instead of proceeding directly to curative treatment, men with nonRA MRI results should strongly consider pMRI Bx since a significant proportion of these men will have RA pMRI Bx results with a positive predictive value only approaching 47%. A good portion of men with nonRA findings would likely have decided against curative therapy if pMRI Bx had been done. Additionally, the limited number of patients with nonRA pMRI Bx after RA MRI suggests that urologists and patients can reasonably trust RA MRI during the shared decision making process.

Ultimately the MRI and pMRI Bx results are only a few of the many factors which go into the shared decision making process when selecting AS vs curative therapy. Of the 133 men with RA MRI results 78 (59%) proceeded directly to AS, 27 (20%) elected curative therapy and 28 (21%) were apparently still unsure how to proceed and obtained pMRI Bx. We extrapolated from these data that urologists and patients overall have confidence in RA MRI results as a confirmatory test. However, this confidence is not absolute as evidenced by the 21% of men with RA MRI results who needed additional reassurance and elected pMRI Bx. This suggests that despite multiple studies demonstrating the strong negative predictive value of RA MRI results,^{16–18} there is added usefulness of pMRI Bx after RA MRI beyond the purpose of finding more aggressive cancer, including building confidence and increasing the proportion of men who elect AS.

There are several limitations worth noting in our study. The registry does not capture certain details such as MRI protocols, MRI lesion volume and software vs cognitive targeting. Additionally, the registry does not differentiate whether positive Bx cores were from the region of interest or the systematic Bx. The number of cores taken of the target or during systematic Bx was not standardized. Although the Roadmap for FRPC advocates MRI for the purpose of considering active surveillance, it is possible that some men may have chosen immediate radical prostatectomy and MRI was obtained by the urologist for surgical planning. Finally, the data are retrospective and the registry may contain errors despite quality monitoring efforts.

Strengths of the study include statewide representation of a diverse set of urology practices. Also, while MUSIC promotes the Roadmap for FRPC,⁴ it leaves decision making up to the individual urologist and patients, allowing for this analysis of decision making. Another strength of the MUSIC registry compared with administrative data sets¹⁹ is the inclusion of a distinct data field for affirmative selection of active surveillance as the management strategy.

CONCLUSIONS

MRI as a confirmatory test performed during the consideration phase of newly diagnosed, favorable risk prostate cancer influences decision making. While RA MRI alone has some impact, pMRI Bx is an even stronger driver, as evidenced by the high proportion of men with RA pMRI Bx results who elected AS regardless of the MRI result.

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EDITORIAL COMMENT



The authors report that a reassuring MRI increased the adoption of active surveillance from 42% to 71% while a reassuring MRI targeted biopsy led to active surveillance in more than 90% of patients.

The definition of "nonreassuring" at MRI targeted biopsy differed in men with GG 1 at initial biopsy (any GG2 is nonreassuring) and those with GG 2 at initial biopsy (more than 3 cores positive and greater than 50% core involvement are nonreassuring). While this is appropriate in the decision making context of an individual who has already made an initial decision for treatment or surveillance based on standard biopsy data and personal preference, it mirrors the inconsistency commonly seen when GG 2 is permitted at entry and when it is a reason for exiting surveillance.

Incorporating MRI and MRI targeted biopsies into an active surveillance strategy will require us

to adopt new ways to risk stratify based on radiological phenotype and MRI targeted biopsy results as well as clinical data and patient preference. The PRECISE (Prostate Cancer Radiological Estimation of Change in Sequential Evaluation) criteria for reporting MRI in active surveillance cases¹ will allow for robust data collection to inform this new approach to risk stratification. It will also facilitate the use of MRI to identify men who could benefit from treatment and enable reduced intensity surveillance in men at lowest risk.

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