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ORIGINAL ARTICLE

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The added influence of genomics and post-MRI confirmatory biopsy results to MRI results alone on medical decision making for men with favorable risk prostate cancer being considered for active surveillance

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Abstract

Background: We examined how the results of genomic classifier (GC) or post-magnetic resonance imaging confirmatory biopsy (pMRI-CBx) influenced management strategy for men with an MRI considering active surveillance (AS).

Methods: We reviewed the Michigan Urological Surgery Improvement Collaborative registry for men with favorable-risk prostate cancer. Among men with an MRI after the diagnostic biopsy ($n = 1162$) a subset also had GC ($n = 126$) or pMRI-CBx ($n = 309$). Results of MRI, GC, and pMRI-CBx were deemed reassuring (RA) or non-reassuring (Non-RA). We assess the association of the combination of test results obtained with the selection of AS. Proportions were compared with the Fisher's exact test. Multivariable logistic regression models were fit for an association of test results with the selection of AS.

Results: The results of pMRI-CBx tended to influence management decisions greater than that of GC, especially in situation where testing results were discordant with the MRI result. Fewer men with a RA MRI and non-RA pMRI-CBx where managed with AS compared with RA MRI alone (31% vs. 86%, $p < 0.001$). non-RA genomics did not seem to have the same influence on management as non-RA pMRI-CBx as a similar proportion of men with RA MRI and non-RA genomics were managed with AS compared with RA MRI alone (85% vs. 86%, $p = 0.753$). More men with non-RA MRI and RA pMRI-CBx were managed with AS compared with non-RA MRI alone (89% vs. 40%, $p < 0.001$). Alternatively, a similar proportion of men with non-RA MRI and RA genomics were managed with AS compared with non-RA MRI alone (42% vs. 40%, $p > 0.999$). In the multivariable models, pMRI-CBx results influenced the decision for AS versus treatment.

Conclusions: In men with newly diagnosed prostate cancer and an MRI, the additional information provided by pMRI-CBx influenced the decision of AS versus treatment, while the addition of GC results were less influential.

Kevin Ginsburg attests to the accuracy of the references and all statements made in the following documents.

KEYWORDS
active surveillance, genomics, magnetic resonance imaging, prostate cancer

1 | INTRODUCTION

Active surveillance (AS) is the preferred management strategy for men with very low risk, low risk, and select men with favorable intermediate risk prostate cancer patients in efforts to avoid the potential unfavorable morbidity associated with definitive interventions.[1–3] Despite the proven oncological efficacy and safety of AS, AS in American men remains unfortunately underutilized.[4,5]

Michigan Urological Surgery Improvement Collaborative (MUSIC) introduced the *Roadmap for Management of Men with Favorable-Risk Prostate Cancer* (FRPC) in 2016 in an effort to aid in the medical-decision making process for men with newly diagnosed prostate cancer considering AS versus treatment.[6] Stressed in the *Roadmap* was the recommendation to obtain at least one early confirmatory test, such as a magnetic resonance imaging (MRI) of the prostate, commercially available genomic classifiers (GC), and/or post-MRI or targeted confirmatory biopsy (pMRI-CBx). The results of these tests, which can be classified as reassuring (RA) or non-reassuring (non-RA), may influence decision-making. Previous work from MUSIC has demonstrated that the additional data point from the results of an early confirmatory test (RA vs. non-RA) can influence treatment-related medical-decision making as well as aid in risk stratification of surveillance outcomes.[7–9]

Since the publication of the *Roadmap*, MRI has also become prevalent in the management of men with the suspicion of or newly diagnosed prostate cancer.[10–13] As the use of MRI becomes increasing more prevalent, there is increasing need to understand the influence of additional confirmatory test results (GC and pMRI-CBx) above and beyond that of the MRI result alone. Herein, we investigated the association of confirmatory test results and the combination of tests results (MRI + GC, MRI + pMRI-CBx, etc.) with the selection of AS as the primary management strategy. From these data, we aim to understand the value of using various confirmatory tests in combination. Furthermore, in the presence of discordant confirmatory test results (such as RA, MRI and non-RA GC or non-RA pMRI-CBx), we can infer the relative importance and influence of the different types of confirmatory tests on treatment related decision-making.

2 | MATERIALS AND METHODS

2.1 | Study design

This is a retrospective review of men with newly diagnosed FRPC in the MUSIC prostate cancer registry. Over 95% of the urologists in the state of Michigan participate in MUSIC, spanning diverse practice settings including small and large academic centers, hospital employed groups, and private practices. Each site obtained Institutional Review Board permission or exemption to participate in MUSIC. This analysis was deemed exempt by the Wayne State Urology Institutional Review Board.

2.2 | Study population

We queried the MUSIC registry for men diagnosed with FPRC between June 2016 and June 2020 who had an MRI within 6 months of the diagnostic biopsy. FRPC was defined as any volume GG1 or low volume GG2 (≤3 cores positive for GG2 and ≤50% of all individual cores positive for GG2) disease. Men with a previous diagnosis of prostate cancer or previous treatment (radiation therapy [RT] or androgen deprivation therapy [ADT]) were excluded.

2.3 | Study objectives

The primary objective was to test for an association of results of confirmatory testing (RA vs. non-RA) and the combination of results of confirmatory tests with the choice of AS versus treatment. While all men had an MRI, some had an additional confirmatory test of GC, pMRI-CBx, or both, in addition to the MRI. pMRI-CBx was defined as biopsies that were obtained within 1 year of diagnosis with or without the use of software based fusion technology. GCs included were the Prolaris cell cycle progression score (Myriad Genetics), the Decipher GC (GenomeDx Biosciences), and the OncotypeDx genomic prostate score (Genomic Health).

The primary dependent variable was the selection of AS defined as the (1) the affirmative selection of AS in the primary medical record and (2) the absence of treatment within 1 year of diagnosis. The primary independent variable was the type and result of the confirmatory testing. The *Roadmap* denotes the results of confirmatory tests as RA versus non-RA.[7,8] Non-RA confirmatory tests were defined as:

- MRI: PIRADS ≥ 4.
- Genomics: (1) Prolaris: >3% probability of prostate cancer mortality; (2) OncoType Dx—<80% freedom from primary Gleason 4; (3) Decipher score >0.45.
- pMRI-CBx: (1) if the diagnostic biopsy was GG1, then any volume GG2 disease was considered non-RA. (2) if the diagnostic biopsy was low volume GG2, then higher volume GG2 disease (>3 cores and >50% of a single core positive for GG2) or any volume GG3 and higher was considered non-RA.

2.4 | Statistical analysis

Cohort baseline characteristics were analyzed with counts and proportions for categorical variables and with medians and

interquartile range for continuous measures. We calculated the proportions of patients on AS by type, results, and combinations of confirmatory tests obtained. Proportions were compared across groups using the Fischer's exact test. To assess the association between confirmatory test results and the selection of AS, we fit a mixed-effects multivariable logistic regression model. The model has both RA MRI alone (Model 1) and non-RA MRI alone (Model 2) as the reference categories. Covariates included in the model were Charlson comorbidity index, race, clinical T stage, biopsy Gleason score, family history of prostate cancer, insurance type, age, body mass index, prostate specific antigen (PSA), number of cores positive for cancer, and greatest percent of an individual core positive for cancer. The model also included random intercepts for each practice to account for within-practice correlation. SAS 9.4 was used for the analysis and statistical significance was set at 0.05.

3 | RESULTS

We identified 1162 men with newly diagnosed FRPC and an MRI (Table 1). Before choosing AS versus treatment, most men in the cohort had an MRI alone ($n = 668$), followed by MRI with pMRI-CBx ($n = 309$), MRI with genomics ($n = 126$), and MRI with genomics and pMRI-CBx ($n = 59$).

First, we investigated men with RA MRI results and other concordant RA test results (Figure 1). A higher proportion of men with RA MRI and RA pMRI-CBx where managed with AS compared with men with RA MRI alone (96% vs. 85%, $p = 0.006$). However, similar proportion of men with RA MRI and RA GC were managed with AS compared with men with an RA MRI alone (86% vs. 86%, $p = 0.856$).

Next, we considered a situation where test results were discordant: men with RA MRI results and other non-RA test results (Figure 1). Fewer men with a RA MRI and non-RA pMRI-CBx (31%) were managed with AS compared with men with a RA MRI alone (86%, $p < 0.001$). However, a similar proportion of men with RA MRI and non-RA genomics were managed with AS (85%) compared with men with a RA MRI alone (86%, $p = 0.753$).

We then evaluated men with non-RA MRI results and other discordant RA test results (Figure 2). We noted more men with non-RA MRI and RA pMRI-CBx were managed with AS (89%) compared with men with a non-RA MRI alone (40%, $p < 0.001$). A similar proportion of men with non-RA MRI and RA genomics (42%) and non-RA MRI alone (40%) were managed with AS ($p > 0.999$).

We then evaluated the scenario of men with non-RA MRI results followed by other concordant non-RA test results (Figure 2). Compared with non-RA MRI alone (40%), there was no significant difference in the proportion of men with non-RA MRI and non-RA pMRI-CBx (35%, $p = 0.494$) or non-RA MRI and non-RA genomics (17%, $p = 0.072$) that were managed with AS.

We fit multivariable logistic regression models to assess if the combination of tests and results were associated with the selection of AS compared with the MRI result alone. In Model 1, RA MRI serves as the reference category to allow us to test if the addition of certain test results were associated with increased odds of choosing AS or treatment compared with RA MRI alone (Table 2A). Men with RA MRI and RA pMRI-CBx had increased odds (odd ratio [OR] 4.79, 95% confidence interval [CI] 1.55–14.74, $p = 0.006$) and men with RA MRI and non-RA pMRI-CBx results had decreased odds of being managed with AS (OR 0.08, 95% CI 0.03–0.27, $p < 0.001$) compared with men with RA MRI alone. Furthermore, we noted men with RA MRI

TABLE 1 Patient demographic and clinical factors

Variable	N(%)/median (IQR)
Race	
White	964 (83%)
African American	101 (8.7%)
Other	22 (1.9%)
Unknown	75 (6.5%)
Insurance	
Private	743 (64%)
Public	413 (36%)
None	3 (0.3%)
Unknown	3 (0.3%)
Family history of PCa	
Yes	362 (31%)
No	753 (65%)
Unknown	47 (4.0%)
Charlson comorbidity index	
CCI = 0	870 (75%)
CCI = 1	156 (13%)
CCI≥ 2	136 (12%)
Biopsy GG	
GG1	930 (80%)
GG2	232 (20%)
Clinical T stage	
T_1	1036 (90%)
T_2 or above	114 (10%)
Age	64.0 (58.0–68.0)
BMI	28.6 (25.8–31.9)
No. positive cores	2.0 (1.0–3.0)
Greatest % cancer involvement	15.0 (5.0–30.0)
Prediagnosis PSA	5.3 (4.3–7.0)
Number of cores sampled	
Diagnostic biopsy	12 (12–12)
pMRI-CBx	16 (14–18)

Abbreviation: BMI, body mass index; IQR, interquartile range.

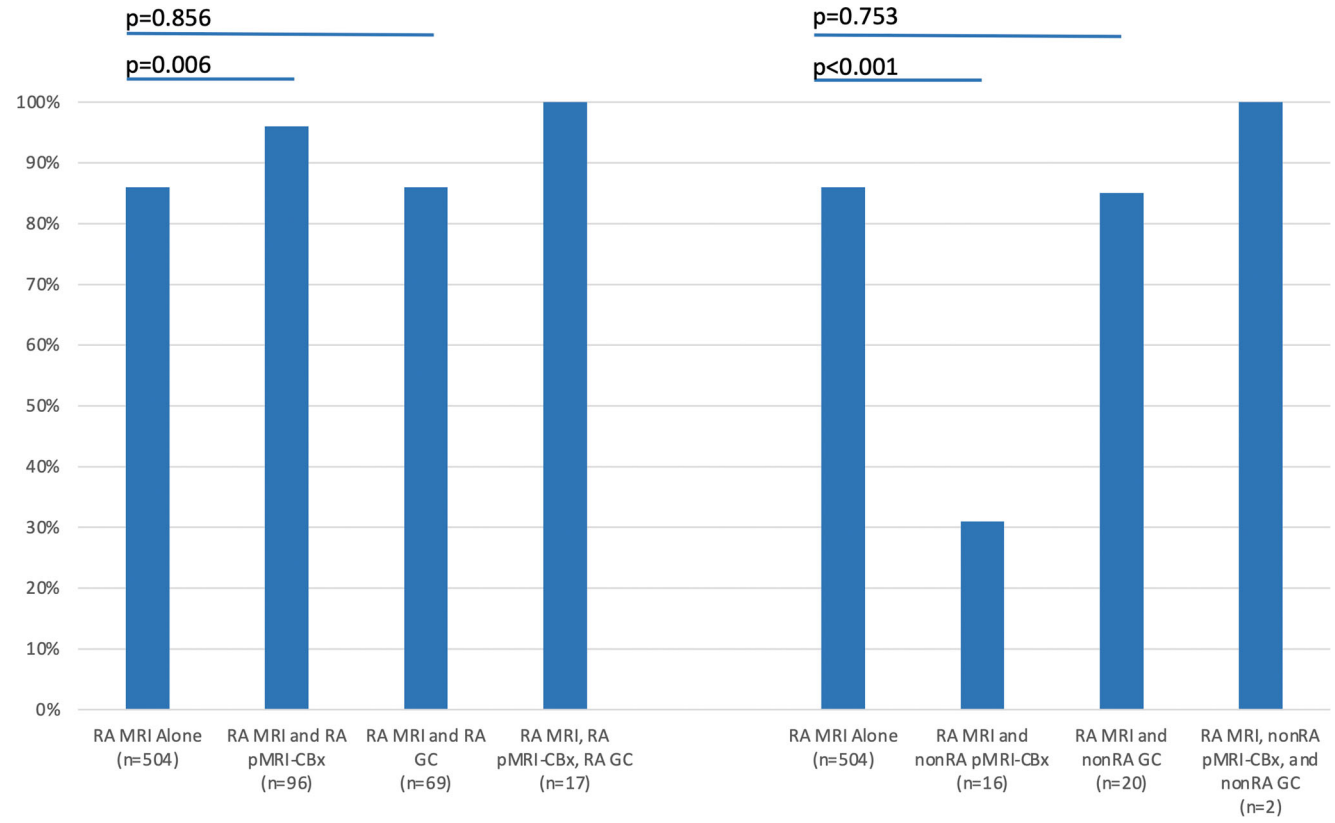

FIGURE 1 Proportion of patients on AS 1 year after diagnosis grouped by the results of genomic classifiers (GC) and post-magnetic resonance imaging confirmatory biopsies (pMRI-CBx) for men with reassuring (RA) MRIs.

followed by RA genomics (OR 1.55, 95% CI 0.67–3.58, $p = 0.308$) or non-RA genomics (OR 3.00, 95% CI 0.61–14.69, $p = 0.175$) had similar odds of being managed with AS compared with RA MRI alone.

In Model 2, non-RA MRI results alone serves as the reference category (Table 2B). Men with non-RA MRI and RA pMRI-CBx had increased odds (OR 10.7, 95% CI 4.84–23.0, $p < 0.001$) and men with non-RA MRI and non-RA pMRI-CBx had decreased odds (OR 0.47, 95% CI 0.25–0.87, $p = 0.016$) of being managed with AS compared with men with non-RA MRI alone. We noted men with non-RA MRI and genomics had similar odds of being managed with AS, regardless if the genomics results were RA (OR 1.49, 95% CI 0.45–4.94, $p = 0.516$) or non-RA (OR 0.36, 95% CI 0.08–1.42, $p = 0.136$ compared with men with non-RA MRI alone.

4 | DISCUSSION

While the National Comprehensive Cancer Network guidelines support the use of tissue based genomic biomarkers to aid in risk stratification for patients with low and intermediate risk prostate cancer, the literature itself is conflicting for those with localized prostate cancer.[1,14–16] While some studies have shown GC to be associated with adverse pathology or biopsy upgrading on AS, other studies have failed to reproduce these finding.[14,17,18] This hesitancy is reflected by AUA's expert opinion in the *Clinically Localized Prostate Cancer* guidelines which state "tissue-based genomic biomarkers have not shown a clear role in the selection of candidates for active surveillance."[3] As the field continues to increasingly utilize peridiagnostic MRI, there is a need to assess how additional confirmatory testing, such as GC and pMRI-CBx, influence medical decision making above the MRI results alone or in combination with MRI results.

Given the rarity of metastasis or death from prostate cancer for men with FRPC on AS,[19,20] it is unlikely that the results of confirmatory tests (MRI, pMRI-CBx, or GC) for men considering AS could improve upon these excellent outcomes. Therefore, to judge the utility and value of these tests, we chose to study how tests results influenced the management strategy for men considering AS versus treatment.[16] We found that pMRI-CBx results heavily influenced the medical decision-making process for AS versus treatment. We noted more men with non-RA MRI and RA pMRI-CBx were managed with AS compared with men with non-RA MRI alone, and more men with RA MRI and non-RA pMRI-CBx chose treatment compared with men with a RA MRI alone. Similarly, in our multivariable models, pMRI-CBx results influenced management strategy above the MRI result alone; there was valuable information garnered from the pMRI-Bx result regardless if the MRI was RA versus non-RA or if the pMRI-CBx result was RA versus non-RA. Alternatively, GC had a relatively insignificant impact on the decision for AS versus treatment above the MRI result alone, as evident by the finding that most men with MRI and GCs were managed similar to the

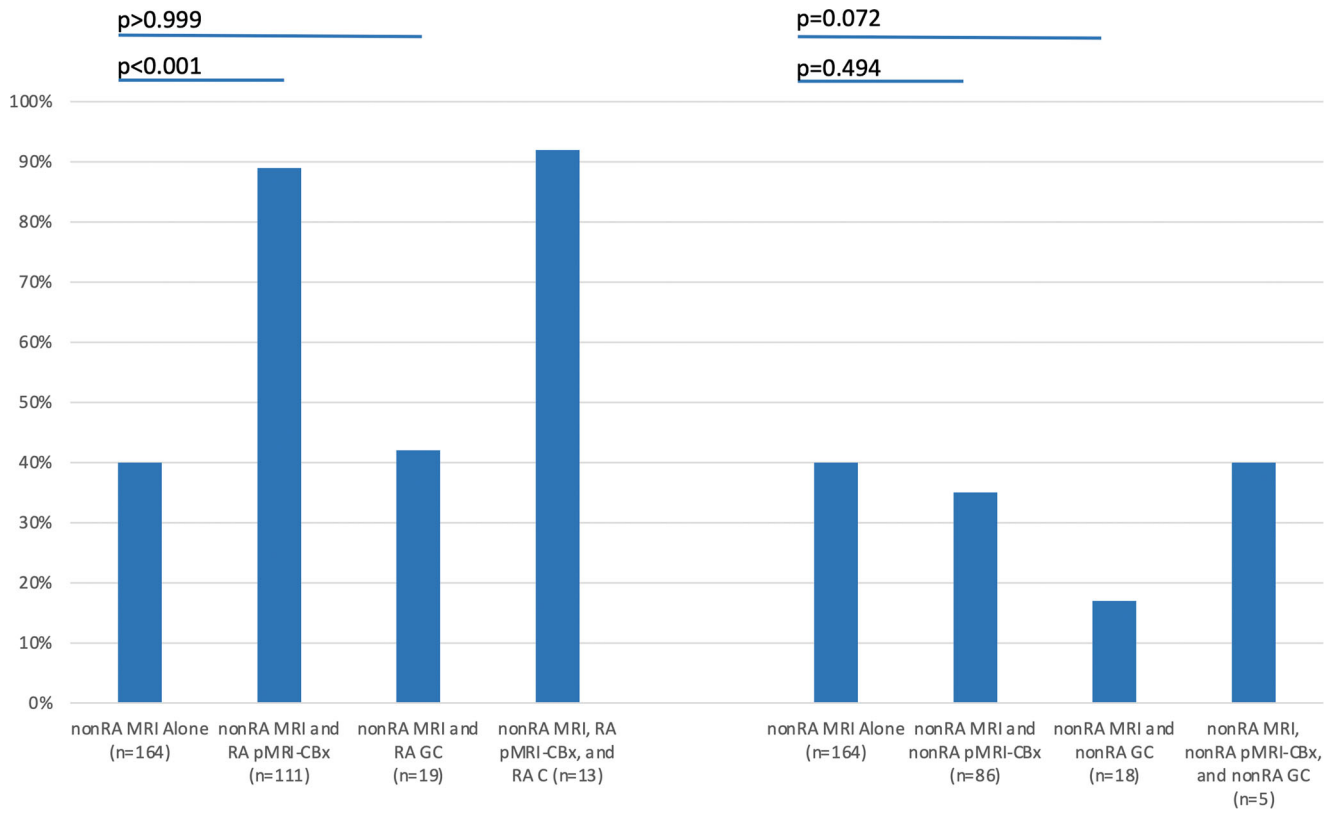

FIGURE 2 Proportion of patients on AS 1 year after diagnosis grouped by the results of genomic classifiers (GC) and post-magnetic resonance imaging confirmatory biopsies (pMRI-CBx) for men with non-reassuring (non-RA) MRIs.

TABLE 2A Multivariable logistic regression model assessing the combination of test results with the selection of active surveillance.*

Confirmatory test result	OR	95% CI	*p* value
RA MRI	Ref	Ref	Ref
RA MRI + RA pMRI-CBx	4.79	1.55, 14.74	0.006
RA MRI + non-RA pMRI-CBx	0.08	0.03, 0.27	<0.001
RA MRI + RA GC	1.55	0.67, 3.58	0.308
RA MRI + non-RA GC	3.00	0.61, 14.69	0.175
Non-RA MRI alone	0.12	0.07, 0.19	<0.001
Non-RA MRI + RA pMRI-CBx	1.28	0.61, 2.65	0.511
Non-RA MRI + non-RA pMRI-CBx	0.06	0.03, 0.10	<0.001
Non-RA MRI + RA GC	0.18	0.06, 0.58	0.004
Non-RA MRI + non-RA GC	0.04	0.01, 0.17	<0.001

Note: RA MRI alone serves as the reference category.

Abbreviations: CBx, confirmatory biopsies; CI, confidence interval; GC, genomic classifiers; OR, odd ratio; pMRI, post-magnetic resonance imaging; RA, reassuring.

*Model adjusted for Charlson comorbidity index, race, clinical T stage, biopsy GG, family history of prostate cancer, insurance type, age, BMI, PSA, number of core positive for cancer, and greatest percent of an individual core for cancer.

TABLE 2B Multivariable logistic regression model assessing the combination of test results with the selection of active surveillance.*

Confirmatory test result	OR	95% CI	*p* value
Non-RA MRI alone	Ref	Ref	Ref
Non-RA MRI + RA pMRI-CBx	10.7	4.94, 23.0	<0.001
Non-RA MRI + non-RA pMRI-CBx	0.47	0.25, 0.87	0.016
Non-RA MRI + RA GC	1.49	0.45, 4.94	0.516
Non-RA MRI + non-RA GC	0.33	0.08, 1.42	0.136
RA MRI alone	8.43	5.27, 13.49	<0.001
RA MRI + RA pMRI-CBx	40.01	12.47, 128.3	<0.001
RA MRI + non-RA pMRI-CBx	0.69	0.21, 2.25	0.535
RA MRI + RA GC	12.9	5.37, 30.74	<0.001
RA MRI + non-RA GC	24.8	4.97, 123.6	<0.001

Note: Non-RA MRI alone serves as the reference category.

Abbreviations: CBx, confirmatory biopsies; CI, confidence interval; GC, genomic classifiers; OR, odd ratio; pMRI, post-magnetic resonance imaging; RA, reassuring.

*Model adjusted for Charlson comorbidity index, race, clinical T stage, biopsy GG, family history of prostate cancer, insurance type, age, BMI, PSA, number of core positive for cancer, and greatest percent of an individual core for cancer.

results of men with an MRI alone, suggesting the additional information of the GC did not change the management form the information learned from the MRI.

Furthermore, when we focus on situations in which the results of the confirmatory tests were discordant (such as RA MRI and non-RA genomics), we can infer about the relative weight and importance of different test results to patients and providers debating between AS versus treatment. In our study, more men with non-RA MRI and RA confirmatory pMRI-CBx results were managed with AS compared with non-RA MRI result alone and more men with RA MRI and non-RA pMRI-CBx results underwent treatment compared with a RA MRI result alone. From these data we can infer the pMRI-CBx result is more influential and important in the medical decision-making process compared with the MRI result as the decision for AS versus treatment aligned with the result of the pMRI-CBx and less of the MRI result alone in scenarios of discordant results. Alternatively, when considering discordant GC and MRI results, management decision seemed to align more with the MRI result than the GC result, suggesting that MRI results are weighted more heavily than GC results.

It is important to consider limitations inherent to this study design. Men were not randomized to the types and combinations of confirmatory tests obtained. The nonrandomized nature of this study allows for an element of selection bias and confounding by indication that may not be controlled for despite multivariable modeling. Understanding the nonrandomized trial design, we attempted to limit heterogeneity as much as possible by limiting the cohort to a subset of patients with newly diagnosed prostate cancer and a postdiagnostic MRI. We purposefully chose to not to include patients with GC alone (GC alone and no MRI) as a comparator group from this analysis as we were concerned that these patients may simply be fundamentally different from patients that were on a postdiagnostic MRI pathway. Additionally, MUSIC does not dictate practice patterns and management decisions. How the results of confirmatory tests were used and management decision were left to the discretion of the urologist and patient. This nonstandardization does allow for us to study and measure how the results of confirmatory tests influence practice patterns. Furthermore, we did not consider the order of tests obtained (MRI before genomics or vice versa). Rather, men were characterized by all test results present before making a decision for AS versus treatment regardless of the order in which they were obtained. The number of biopsy cores taken during the systematic biopsy or cores per region of interest was left to the discretion of the managing urologists and not standardized. Despite these limitations, this is the first study to assess how the results of multiple types of early confirmatory tests influence the decision for AS versus treatment in a large, diverse prostate cancer cohort.

5 | CONCLUSIONS

In men with an MRI considering AS, results of pMRI-CBx strongly influenced the decision for AS versus treatment and provided additional actionable information above that of the MRI result alone. Results of GC in combination with MRI were less influential in the decision for AS versus treatment compared with the MRI result alone. Urologists and prostate cancer specialists may consider these data when elucidating the role of additional testing for patients considering AS that have already obtained an MRI.

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CONFLICTS OF INTEREST

J. Q., A. K. G., A. S., and S. M. L. received salary support through MUSIC. The remaining authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data for this study are not publicly available due to privacy and ethical restrictions.

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