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Biparametric vs Multiparametric MRI for Prostate Cancer Diagnosis
The PRIME Diagnostic Clinical Trial

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IMPORTANCE Multiparametric magnetic resonance imaging (MRI), with or without prostate biopsy, has become the standard of care for diagnosing clinically significant prostate cancer. Resource capacity limits widespread adoption. Biparametric MRI, which omits the gadolinium contrast sequence, is a shorter and cheaper alternative offering time-saving capacity gains for health systems globally.

OBJECTIVE To assess whether biparametric MRI is noninferior to multiparametric MRI for diagnosis of clinically significant prostate cancer.

DESIGN, SETTING, AND PARTICIPANTS A prospective, multicenter, within-patient, noninferiority trial of biopsy-naive men from 22 centers (12 countries) with clinical suspicion of prostate cancer (elevated prostate-specific antigen [PSA] level and/or abnormal digital rectal examination findings) from April 2022 to September 2023, with the last follow-up conducted on December 3, 2024.

INTERVENTIONS Participants underwent multiparametric MRI, comprising T2-weighted, diffusion-weighted, and dynamic contrast-enhanced (DCE) sequences. Radiologists reported abbreviated biparametric MRI first (T2-weighted and diffusion-weighted), blinded to the DCE sequence. After unblinding, radiologists reported the full multiparametric MRI. Patients underwent a targeted biopsy with or without systematic biopsy if either biparametric MRI or multiparametric MRI was suggestive of clinically significant prostate cancer.

MAIN OUTCOMES AND MEASURES The primary outcome was the proportion of men with clinically significant prostate cancer. Secondary outcomes included the proportion of men with clinically insignificant cancer. The noninferiority margin was 5%.

RESULTS Of 555 men recruited, 490 were included for primary outcome analysis. Median age was 65 (IQR, 59-70) years and median PSA level was 5.6 (IQR, 4.4-8.0) ng/mL. The proportion of patients with abnormal digital rectal examination findings was 12.7%. Biparametric MRI was noninferior to multiparametric MRI, detecting clinically significant prostate cancer in 143 of 490 men (29.2%), compared with 145 of 490 men (29.6%) (difference, −0.4 [95% CI, −1.2 to 0.4] percentage points; $P = .50$). Biparametric MRI detected clinically insignificant cancer in 45 of 490 men (9.2%), compared with 47 of 490 men (9.6%) with the use of multiparametric MRI (difference, −0.4 [95% CI, −1.2 to 0.4] percentage points). Central quality control demonstrated that 99% of scans were of adequate diagnostic quality.

CONCLUSION AND RELEVANCE In men with suspected prostate cancer, provided image quality is adequate, an abbreviated biparametric MRI scan, with or without targeted biopsy, could become the new standard of care for prostate cancer diagnosis. With approximately 4 million prostate MRIs performed globally annually, adopting biparametric MRI could substantially increase scanner throughput and reduce costs worldwide.

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Supplemental content

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In the past 5 years, multiparametric magnetic resonance imaging (MRI) with or without prostate biopsy has become the international standard of care for prostate cancer diagnosis.[1-3] A multiparametric MRI scan consists of 3 sequences: T2-weighted, diffusion-weighted, and dynamic contrast-enhanced (DCE) sequences. However widespread adoption is challenging due to resource issues and increased demand for prostate MRI.[4,5]

One solution is to adopt a shorter, less resource-intensive scan without the DCE sequence,[6,7] known as biparametric MRI. This reduces scan time from 30 to 40 minutes to 15 to 20 minutes, thus increasing scanning capacity.[6,8,9] Using contrast medium for multiparametric MRI necessitates a medical practitioner to be present in case of an allergic reaction, meaning that by avoiding a patient injection, biparametric MRI is less resource intensive in terms of staff and scanner time. Further, it is known that the contrast medium used, gadolinium, deposits in the brain, bone, liver, and skin.[10,11] In addition to the cost of the contrast medium and its administration, gadolinium contamination of the environment has been observed.[11]

Most studies comparing biparametric MRI to multiparametric MRI are typically small, single-center, unblinded retrospective studies without MRI quality assurance.[7,12,13] They typically use a scoring system[14] that already assumes that the DCE sequences have a limited role in cancer detection, limiting their ability to show a difference in cancer detection.[15] Further, biopsies were typically either not targeted to MRI-suspicious areas or were performed on the basis of the full multiparametric MRI information only, without considering what would have been done without the sequences. The only randomized trial comparing biparametric MRI with multiparametric MRI showed significant cancer detection in favor of multiparametric MRI (24% vs 33%) but without statistical significance due to being underpowered.[16] Genuine uncertainty remains as to whether DCE sequences improve significant cancer detection. Contrast is also thought to play an important role in staging decisions and evaluating involvement of key anatomical structures around the prostate, thus influencing treatment eligibility options and treatment planning.[17,18]

The Prostate Imaging using MRI ± Contrast Enhancement (PRIME) trial was designed to overcome these limitations[15,19] and investigate whether biparametric MRI is noninferior to multiparametric MRI for the detection of clinically significant prostate cancer.

Key Points

Question Is biparametric magnetic resonance imaging (MRI) noninferior to multiparametric MRI in the detection of clinically significant prostate cancer?

Findings In this level-1, prospective, multicenter, within-patient, noninferiority trial of 490 biopsy-naive men, biparametric MRI was noninferior to multiparametric MRI for detection of Gleason Grade Group 2 or higher prostate cancer (difference, −0.4 percentage points).

Meaning In men with suspected prostate cancer, provided that image quality is adequate, an abbreviated biparametric MRI, with or without targeted biopsy, could become the new standard of care for prostate cancer diagnosis.

Methods

Trial Design

PRIME was a prospective, international, multicenter, within-patient, noninferiority, level-1 evidence diagnostic yield study conducted in 22 centers in 12 countries (eTable 1 in Supplement 3). A diagnostic yield study is one that evaluates and compares the proportion of participants with a target condition detected by different diagnostic tests. Men who provided written informed consent were enrolled into the study and underwent multiparametric MRI. The trial protocol has been published[19] and was approved by the ethical review board at each participating institution (Supplement 1). The statistical analysis plan is available in Supplement 2. The trial was monitored by an independent global trial steering committee.

Participants

Participants were recruited in outpatient clinics and were eligible if they were referred with clinical suspicion of prostate cancer based on elevated prostate-specific antigen (PSA) level or abnormal digital rectal examination findings (eg, prostate nodule or firm prostate) (**Figure 1**). Participants were required to have a PSA level 20 ng/mL or lower and no prior MRI or biopsy. Self-reported ethnicity data were collected on enrollment using predefined categories to characterize the ethnic composition of the study cohort (**Table 1**).

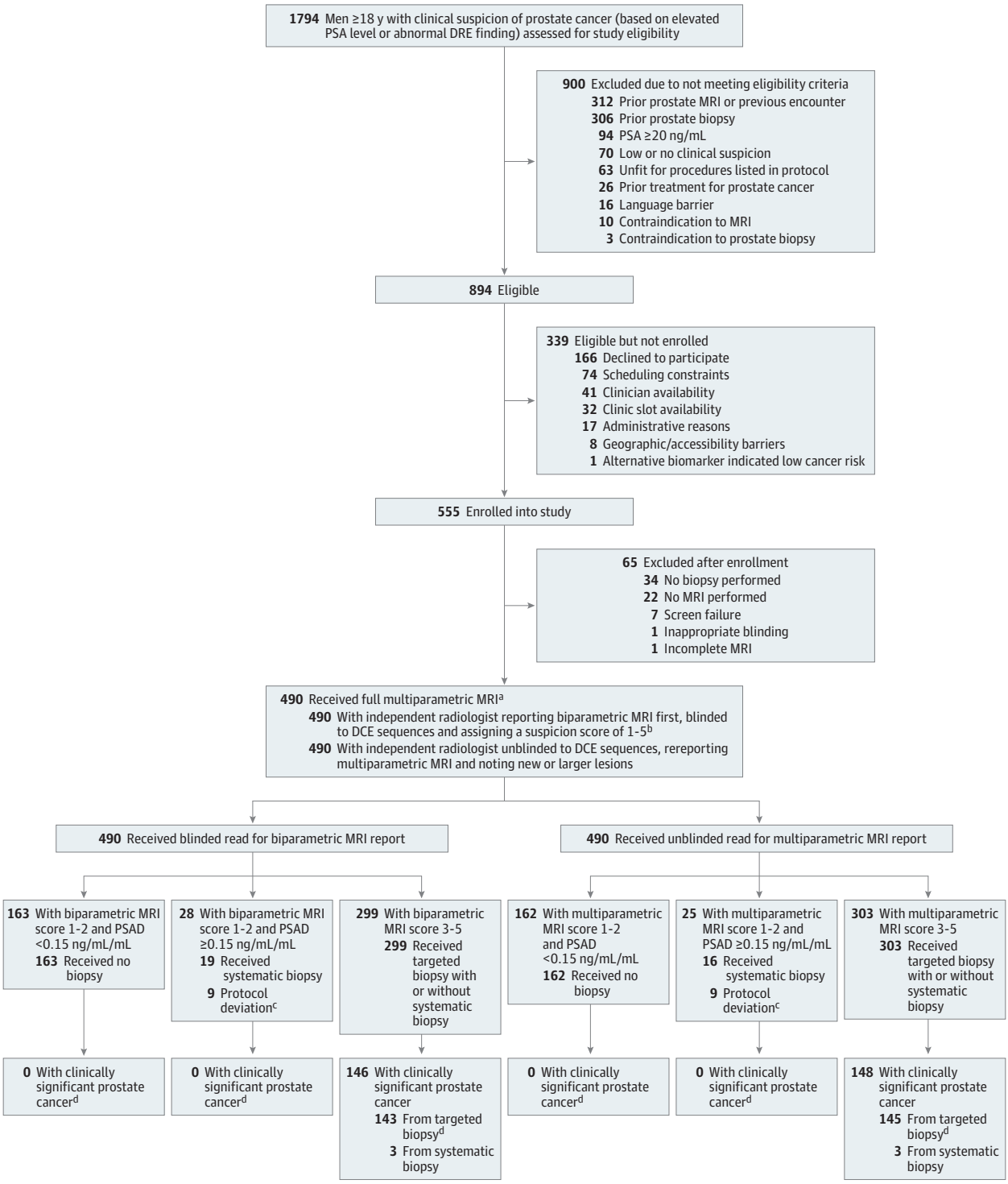
MRI and Prostate Biopsy

Patients underwent multiparametric MRI using a 1.5T or 3.0T scanner with a pelvic phased-array coil, with or without an endorectal coil (eTable 2 in Supplement 3). T2-weighted, diffusion-weighted, and DCE sequences were acquired according to Prostate Imaging–Reporting and Data System version 2.1 (PI-RADSv2.1) guidelines.[14] Image quality for each scanner was optimized to be guideline compliant at each site.[13]

A site radiologist first evaluated the biparametric MRI (T2-weighted and diffusion-weighted imaging), strictly blinded to DCE sequences (Figure 1). Successful blinding was confirmed for each case by an independent clinician or dedicated computer workflow. Suspicious areas on biparametric MRI were identified by the radiologist and assigned a score according to the Likert[20] and PI-RADSv2.1 scoring systems[14] on a scale from 1 to 5, with higher numbers indicating a greater likelihood of clinically significant prostate cancer. Both scoring systems were defined as 1 (highly unlikely), 2 (unlikely), 3 (equivocal), 4 (likely), and 5 (highly likely) to contain clinically significant prostate cancer. Radiologists were mandated to record the biparametric MRI–based decision and biopsy-target recommendations before the DCE sequences were revealed. This allowed an unbiased assessment of the stand-alone contribution of biparametric MRI to cancer detection.

After immediate unblinding to the DCE sequences, the radiologist reevaluated all 3 sequences and generated a new multiparametric MRI report. If a completely new suspicious region was identified that was absent on biparametric MRI, or if

Figure 1. Flow of Participants in the PRIME Trial



DRE indicates digital rectal examination; prostate-specific antigen; PSAD, prostate-specific antigen density.

[a]Radiologists first reported the biparametric MRI (T2-weighted sequence + diffusion-weighted sequence), blinded to dynamic-contrast enhanced (DCE) sequences, and generated a biparametric MRI report. After immediate unblinding to DCE sequences, radiologists reevaluated all sequences and generated a multiparametric MRI report, marking any new suspicious regions or significantly larger lesions separately.

[b]Each MRI lesion is scored 1-5, representing the likelihood of clinically significant prostate cancer using both Likert and Prostate Imaging Reporting and Data System version 2.1 scoring systems, with the highest score on either system determining the subsequent pathway. A score of 1 indicates clinically significant cancer is highly unlikely, 3 is equivocal, and 5 indicates it is highly likely.

[c]Nine participants with no lesions on biparametric MRI and multiparametric MRI, but a PSA density ≥0.15, did not have systematic biopsy.

[d]Defined as presence of any cancer with Gleason Grade Group ≥2. The Gleason system ranges from 1 (least aggressive) to 5 (most aggressive).

Table 1. Baseline Characteristics of Participants

Characteristic	All participants (N = 490)
Age, median (IQR), y	65 (59-70)
Ethnicity (self-reported), No. (%)	
Asian	17 (3.5)
Black (African or Caribbean)	20 (4.1)
Mixed or multiple	2 (0.4)
Other[a]	14 (2.9)
White	437 (89.2)
Obesity (BMI >30), No. (%)[b]	32 (6.5)
Medical history, No. (%)	
Family history of prostate cancer	92 (18.8)
Diabetes without organ damage	26 (5.3)
Taking blood thinning medication	23 (4.7)
Chronic pulmonary disease	15 (3.1)
Myocardial infarction	12 (2.5)
Any tumor within last 5 y	10 (2.0)
Cerebrovascular disease	10 (2.0)
Peripheral vascular disease	10 (2.0)
Diabetes with organ damage	2 (0.6)
Abnormal digital rectal examination, No. (%)[c]	62 (12.7)
PSA, median (IQR), ng/mL	5.6 (4.4-8.0)
WHO performance status, No. (%)[d]	
0: Fully active	469 (95.7)
1: Restricted in strenuous activity	20 (4.1)
2: Self-caring but unable to work	1 (0.2)

Abbreviations: BMI, body mass index; PSA, prostate-specific antigen; WHO, World Health Organization.

[a] Other (n = 14) includes men that self-reported their ethnicity as Arabic-Asian (n = 1), Chinese (n = 1), Hispanic (n = 1), Inder (n = 1), South Asian (n = 1), Turkish (n = 1), or not disclosed (n = 8).

[b] BMI calculated as weight in kilograms divided by square of height in meters.

[c] A subjective clinical examination finding suggestive of prostate cancer, eg, a prostate nodule or firm prostate.

[d] A scale to assess a patient's functional ability, ranging from 0 (fully active) to 5 (dead). Higher scores indicate a greater degree of disability.

an existing biparametric MRI lesion appeared significantly larger on multiparametric MRI, the newly revealed region (or nonoverlapping portion of the enlarged lesion) was marked as a separate, DCE sequence–specific target for biopsy.

Areas on either biparametric MRI or multiparametric MRI suggestive of cancer, scoring 3 (equivocal for clinically significant prostate cancer), 4 (likely for clinically significant prostate cancer), or 5 (highly likely for clinically significant prostate cancer) on either the Likert or PI-RADSv2.1 scores underwent targeted prostate biopsy. Systematic biopsies were taken on MRI-negative sides of the prostate.

If the MRI was not suggestive of clinically significant prostate cancer, scoring 1 or 2 on both the Likert and PI-RADSv2.1 scales, bilateral systematic biopsies were taken if there was high clinical suspicion of prostate cancer, with a PSA density of 0.15 ng/mL/mL or greater. With a PSA density less than 0.15 ng/mL/mL, no prostate biopsy was taken.

MRI-targeted biopsy registration was performed by visual or software-assisted registration[21,22] via the transperineal or transrectal route, according to local expertise. Biopsy operators took 4 cores from each suspicious area on MRI. The full biopsy schema is in the protocol.[19]

eTable 3 in Supplement 3 provides details regarding the experience of the clinicians in the trial.

Outcomes

The primary outcome was the proportion of men with clinically significant prostate cancer, defined as the presence of a single biopsy core indicating disease of Gleason Grade Group 2 or greater (the range for Gleason Grade Group is 1 to 5, with higher scores indicating a more aggressive form of prostate cancer). Secondary outcomes included the proportion of men with clinically insignificant cancer (Gleason Grade Group 1), test performance, and the proportion of patients in whom DCE sequences made a difference in treatment eligibility or planning. The secondary outcomes are listed in eTable 4 in Supplement 3. Outcomes were reported according to the START[21] and STARD[23] guidelines (eTables 5 and 6 in Supplement 3).

Follow-Up

Participants were followed up until their treatment decision. Participants who underwent further diagnostic tests or treatment were followed up until after these procedures. Patients with negative test results returned to standard-of-care PSA monitoring.

Multidisciplinary Team Meeting

Radiologists, oncologists, and urologists involved in the delivery of radiotherapy, surgery, focal therapy, or active surveillance for prostate cancer led dedicated trial mutidisciplinary team meetings. Treatment eligibility options and detailed treatment planning by individual treatment modality were discussed for each participant based on their clinical information including patient-reported outcome measures, biparametric MRI images, and prostate biopsy results, blinded to any information from the DCE sequences or DCE-specific biopsies.[19] The group was then unblinded to the DCE sequences and DCE-specific biopsies and reevaluated the participants' treatment options and planning.

Patient-Reported Outcome Measures

Participants completed baseline International Index of Erectile Function 5 and International Prostate Symptom Score questionnaires[24,25] to ascertain erectile function and lower urinary tract symptoms.

Central Quality Control

Following completion of the trial, radiologists and pathologists at the coordinating center, unaware of the results of the original reports, reviewed all the MRIs and 15% of the original pathological specimens, chosen at random from participants at each site. MRIs were evaluated using the PI-QUAL (Prostate Imaging Quality) scoring system[26] on a scale from 1 to 5, with higher numbers indicating a higher-quality scan.

Statistical Analysis

The statistical analysis plan (Supplement 2) was prespecified and approved by the clinical trial group lead, statistician, and chief investigator, prior to data analysis.

Table 2. Comparison of Outcomes Between Biparametric and Multiparametric MRI[a]

Outcome	No. (%) [95% CI]		Difference (95% CI), percentage points[b]
	Biparametric MRI (n = 490)	Multiparametric MRI (n = 490)	
Clinically significant cancer (primary outcome)[c]	143 (29.2) [25.2 to 33.4]	145 (29.6) [25.6 to 33.9]	−0.4 (−1.2 to 0.4) [*P* = .50]
Gleason Grade Group			
2[d]	70 (14.3)	70 (14.3)	
3	39 (8.0)	40 (8.2)	
4	13 (2.7)	13 (2.7)	
5	21 (4.3)	22 (4.5)	
Clinically insignificant cancer (Gleason Grade Group 1) (secondary outcome)	45 (9.2) [6.8 to 12.1]	47 (9.6) [7.1 to 12.6]	−0.4 (−1.2 to 0.4)
Proportion of patients with biopsy indication[e]	273 (55.7) [51.2 to 60.2]	280 (57.1) [52.6 to 61.6]	−1.4 (−3.4 to 0.5)
Proportion of patients with no biopsy indication[e]	217 (44.3)	210 (42.9)	1.4 (−0.5 to 3.4)
No cancer on biopsy (benign)	85 (17.3)	88 (18.0)	−0.7 (−2.2 to 1.4)

[a] See eTables 16, 17, and 18 in Supplement 3 for magnetic resonance imaging and pathology quality assessments.

[b] Difference between rates are shown in percentage points.

[c] As per primary outcome definition of clinically significant cancer, which was defined as the presence of a single biopsy core indicating disease of Gleason Grade Group 2 or greater. It was assessed for noninferiority of biparametric MRI compared with multiparametric MRI with a prespecified margin of 5 percentage points. Clinically insignificant cancer was therefore defined as the presence of disease only of Gleason Grade Group 1.

[d] The Gleason Grade Group system classifies prostate cancer based on glandular architecture seen on histology from biopsy. It is derived from the sum of the 2 most common Gleason patterns (each scored 1-5), then mapped to a Grade Group from 1 to 5, where higher groups indicate more aggressive disease. Specifically, Gleason Grade Group 1 = Gleason ≤6 (3 + 3; clinically insignificant cancer); Gleason Grade Group 2 = Gleason 7 (3 + 4); Gleason Grade Group 3 = Gleason 7 (4 + 3); Gleason Grade Group 4 = Gleason 8 (4 + 4, 3 + 5 or 5 + 3); Gleason Grade Group 5 = Gleason 9-10 (4 + 5, 5 + 4, or 5 + 5).

[e] As indicated by a Likert score of 3 or greater.

Using a noninferiority margin of 5 percentage points and a 1-sided α level of 2.5%, a sample of 400 men would provide 90% power to show noninferiority of biparametric MRI to multiparametric MRI, assuming a multiparametric MRI underlying probability of detecting clinically significant cancer of 38%. This sample size was increased to 500 to allow for a 20% rate of dropout or exclusion after enrollment. A noninferiority margin of 5 percentage points was chosen following a consensus meeting of clinicians and patients. This was determined to be the clinically acceptable trade-off between a small potential drop in cancer detection against the substantial practical, safety, and economic benefits of biparametric MRI over multiparametric MRI. Detailed justification of the sample size is provided in the protocol (Supplement 1).

For the primary outcome, the proportion of men with clinically significant prostate cancer detected by biparametric MRI-targeted biopsy was defined as the number of men with clinically significant prostate cancer identified on biparametric MRI-targeted biopsy divided by the number of men undergoing biparametric MRI. Similarly, the proportion of men with clinically significant prostate cancer detected by multiparametric MRI-targeted biopsy was defined as the number of men with clinically significant prostate cancer identified on multiparametric MRI-targeted biopsy divided by the number of men undergoing multiparametric MRI. For the primary outcome, the Likert score was used to derive a suspicious MRI requiring MRI-targeted biopsy and planned sensitivity analyses were performed using the PI-RADSv2.1 scale. Detailed derivation of the status of each patient is provided in the statistical analysis plan (Supplement 2). A *P* value was obtained using a McNemar test.

A sensitivity analysis of the primary outcome was performed using a more stringent definition of clinically significant prostate cancer of any core containing tissue of Gleason grade group 3 or greater.

For secondary outcomes, the results are reported as point estimates with 95% CIs. The widths of the CIs were not adjusted for multiplicity, so the intervals should not be used for inference. Further analysis details are provided in eSection 3 in Supplement 3.

Results

Trial Population

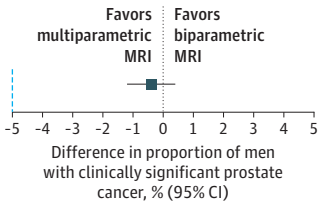
From April 2022 through September 2023, 555 men were enrolled into the study from 22 centers in 12 countries. Of these, 490 men (median age, 65 [IQR, 59-70] years; median PSA level, 5.6 [IQR, 4.8-8.0] ng/mL; 12.7% with abnormal digital rectal examination findings) were eligible for the primary outcome analysis (Figure 1). Baseline characteristics of the population are reported in Table 1.

MRI scans were carried out on 39 scanners (435/490 [88.8%] on 3.0-tesla [3.0T] scanners), reported by 30 radiologists (eTable 7 in Supplement 3). MRI identified 308 of 490 men (62.9%) with at least 1 suspicious area for biopsy. In those men, the median number of suspicious areas identified was 2 (IQR, 1-2). Of men undergoing biopsy, 193 of 319 biopsies (60.5%) were performed via the transperineal route and 260 of 319 (81.5%) using software-assisted or fusion registration (eTables 8 and 9 in Supplement 3).

Outcomes

The proportion of scans scoring 3 or greater on the Likert scale leading to a biopsy indication was 273 of 490 (55.7%) for biparametric MRI and 280 of 490 (57.1%) for multiparametric MRI

Figure 2. Difference in Proportion of Men With Clinically Significant Prostate Cancer Between Biparametric MRI and Multiparametric MRI, With Noninferiority Margin and 95% CI



Difference in proportion of men with clinically significant prostate cancer, −0.40 (95% CI, −1.20 to 0.40) percentage points. The lower bound of the 95% confidence interval does not cross the noninferiority margin (blue vertical dashed line), indicating that biparametric magnetic resonance imaging (MRI)–targeted biopsy is noninferior to multiparametric MRI–targeted biopsy.

(difference, −1.4 percentage points) (**Table 2**; eTable 10A in Supplement 3). DCE sequences identified newly suspicious areas in 31 of 490 patients (6.3%). Of these 31 patients, 21 (67.7%) had a suspicious area not visible on biparametric MRI, and 10 (32.3%) had a suspicious area that was significantly larger on multiparametric MRI. Twenty-nine of 31 patients (93.5%) derived no additional detection of clinically significant prostate cancer from the DCE sequences-specific biopsy.

Biparametric MRI was noninferior to multiparametric MRI for detection of clinically significant prostate cancer, detecting 143 of 490 men (29.2%), compared with 145 of 490 men (29.6%) for multiparametric MRI (difference, −0.4 percentage points [95% CI, −1.2 to 0.4]; P = .50) (**Figure 2**). This result was consistent in the sensitivity analysis using Gleason Grade Group 3 or higher to define clinically significant prostate cancer (difference, −0.4 percentage points [95% CI, −1.2 to 0.4]) (eTable 11 in Supplement 3).

For clinically insignificant cancer detection, biparametric MRI detected cancer in 45 of 490 men (9.2%), compared with 47 of 490 men (9.6%) with use of multiparametric MRI (difference, −0.4 percentage points [95% CI, −1.2 to 0.4]). Biopsy outcomes and test performance characteristics are reported in Table 2 and **Figure 3**.

Sensitivity, specificity, and positive and negative predictive values were similar for biparametric MRI (98.0%, 61.6%, 53.1%, 98.6%, respectively) and multiparametric MRI (99.3%, 60.1%, 52.5%, 99.5%, respectively) (Figure 3; eTable 12 in Supplement 3). There were no major differences in sensitivity (difference, −1.4 percentage points [95% CI, −3.9 to 1.2]) or specificity (difference, 1.5 percentage points [95% CI, −1.2 to 4.2]). Results were consistent when using the PI-RADSv2.1 scoring system instead of the Likert scoring system (eTable 10B and eTable 12 in Supplement 3).

Radiological T-staging decisions, likelihood of extracapsular extension, and involvement of the bladder neck, seminal vesicle, urethral sphincter, and rectal wall were very similar between biparametric MRI and multiparametric MRI (eTables 13 and 14 in Supplement 3).

After review at the posttrial multidisciplinary team meeting with rotating clinician panels, DCE sequences or DCE sequence-specific biopsies made a difference in treatment eligibility decisions in 21 of 488 cases (4.3% [95% CI, 2.7%-6.5%]) and treatment planning decisions—for example, in how surgery, radiotherapy, or focal therapy were planned to be delivered, in 15 of 488 cases (3.1% [95% CI, 1.7%-5.0%]) (eTable 15 in Supplement 3).

Central review of image quality (eTable 16 in Supplement 3) revealed 482 of 488 scans (98.8%) were of adequate diagnostic quality, scoring 3 or higher on the PI-QUALv1 scale. In those 143 of 488 (29.3%) without optimal diagnostic quality scans—scoring 4 or lower—117 of 143 (81.8%) had an issue with the quality of the T2-weighted or diffusion-weighted sequences and 49 of 143 (34.3%) had an issue with the quality of the DCE sequences (eTable 17A and 17B in Supplement 3). Central quality review of biopsy specimens is outlined in eTable 18 in Supplement 3.

For both biparametric MRI and multiparametric MRI with or without targeted biopsy, clinically significant prostate cancer would have been missed by a targeted-only biopsy approach and detected by systematic biopsy in 3 of 476 (0.6% [95% CI, 0.1 to 1.8]) of patients (eTable 19A and 19B in Supplement 3), leading to a total prevalence of clinically significant prostate cancer in the cohort of 148 of 490 (30.2% [95% CI, 26.2%-34.5%]).

Adverse events are described in eTable 20 in Supplement 3.

Discussion

The PRIME study demonstrates that a shorter and less resource-intensive biparametric MRI detects as much clinically significant cancer as the full multiparametric MRI, without increasing the diagnosis of clinically insignificant cancer. Despite earlier concerns that lack of contrast information would lead to more biopsy recommendations, this study found no evidence of this, with biopsy rates being very similar between biparametric MRI and multiparametric MRI. Although DCE sequences identified a small proportion of new suspicious areas on the multiparametric MRI not seen on the biparametric MRI, the majority of these did not reveal significant cancer; overall, test performance characteristics were also very similar between both biparametric MRI and multiparametric MRI.

With approximately 4 million prostate MRIs performed annually, these findings have critical global health implications,[4] and saving a significant proportion of scanner time and staff time should increase access to imaging and represent a major opportunity cost saving. The significant benefits of a biparametric MRI approach include a shorter scan for the patient, improved scanner throughput for the health care system, avoiding the need for gadolinium contrast, elimination of cannulation and contrast-agent safety risks, avoiding the need for a physician to be present during scanning, and reduced environmental toxicity.[6,11,27]

DCE sequences have been thought to be particularly important in the local staging of prostate cancer and involvement of key anatomical structures around the prostate.[17,18] However, biparametric MRI did not really differ from multipa-

Figure 3. Test Performance Characteristics of Biparametric and Multiparametric MRI

A Biparametric MRI

MRI result	Prostate cancer present	Prostate cancer absent	
Positive	145	128	273
Negative	3	205	208
	148	333	481

	No./total	% (95% CI)
Sensitivity	145/148	98.0 (94.2-99.6)
Specificity	205/333	61.6 (56.1-66.8)
PPV	145/273	53.1 (47.0-59.2)
NPV	205/208	98.6 (95.8-99.7)

B Multiparametric MRI

MRI result	Prostate cancer present	Prostate cancer absent	
Positive	147	133	280
Negative	1	200	201
	148	333	481

	No./total	% (95% CI)
Sensitivity	147/148	99.3 (96.3-100.0)
Specificity	200/333	60.1 (54.6-65.4)
PPV	147/280	52.5 (46.5-58.5)
NPV	200/201	99.5 (97.3-100)

Contingency tables cross-tabulate the magnetic resonance imaging (MRI) result (positive defined as a Likert score ≥3, or negative) against the final histological diagnosis of clinically significant prostate cancer being present or absent. Analyses for diagnostic performance were performed on n = 481 of 490 participant cohort, excluding 9 participants who did not undergo systematic biopsy as per protocol. Difference in sensitivity (biparametric – multiparametric), −1.4% (95% CI, −3.9% to 1.2%). Difference in specificity (biparametric – multiparametric), 1.5% (95% CI, −1.2% to 4.2%). NPV indicates negative predictive value; PPV, positive predictive value.

rametric MRI in this evaluation. Furthermore, the use of DCE sequences changed treatment eligibility decisions or treatment planning decisions in only a minority of cases.

Additional findings include that systematic biopsy on MRI-negative sides of the prostate identified only a very small proportion of men with significant cancer and could likely be omitted.

A previous randomized trial showed an approximate 9% increase in significant cancer detection in favor of multiparametric MRI, which was not observed here.[16] Further, the findings from PRIME are consistent with those from most published studies comparing biparametric MRI and multiparametric MRI,[7,12,15] although those studies had major limitations.

Strengths of PRIME include its design as an appropriately powered prospective multicenter study in many different health care settings and its use of optimized DCE sequences prior to commencing the study to give the best chance of demonstrating any possible added value of contrast.[13] The study design ensured strict blinding of radiologists, who had to submit their biparametric MRI findings and biopsy plans before being shown the contrast sequences. Biopsies were performed based not just on what the multiparametric MRI suggested but also what the biparametric MRI suggested. For the first time, the study evaluated the added value of DCE sequences in treatment decision eligibility and planning in a blinded multidisciplinary team meeting. The primary analysis was also carried out using the Likert scoring system, which permits radiologists to weight findings from DCE sequences higher than with the PI-RADSv2.1 scoring scale, thus realistically permitting a difference between a man being offered a biopsy or not. Centers were permitted to use their local expertise with respect to radiologists, biopsy operators, biopsy access route, and registration technique, which increases the generalizability of the results.

A randomized design was considered, but a within-patient trial design was chosen because it had a number of advantages[19]: first, the patient group and funding peer-reviewed panel preferred this trial design because if one of the techniques was inferior, patients in a randomized design would be denied the benefit of targeted biopsies from the other study group. Second, the within-patient design is a more efficient trial design, requiring a 7-fold lower sample size with equivalent quality of evidence in a diagnostic study. Third, patients act as their own controls, therefore allowing conclusions regarding the value of DCE sequences on a per-patient level. Fourth, it allows for the evaluation of the impact of contrast on staging decisions and treatment eligibility decisions at an individual-patient level.

Limitations

This study had limitations. First, MRI quality was good in PRIME, because participating sites' protocols had been optimized prior to taking part.[13] Thus, centers are advised to ensure that their scans are of good quality prior to considering adopting a biparametric MRI approach. The pre-trial quality control, which included both academic and nonacademic centers globally, suggests that provided that an MRI scanner is less than 10 years old, it is very feasible to deliver optimal scan quality, compliant with international standards, with simple optimization,[13] regardless of whether the center is academic, or whether centers possess 1.5T or 3.0T scanners. This study has demonstrated that this can be achieved without any cost requirements to upgrade equipment and with basic modifications to scanning protocols in line with international guidelines on minimal standards for MRI conduct[13]; thus, this should be achievable in most centers. Further, the approach taken to optimize scan quality before the trial may have given results in favor of multiparametric MRI detecting more cancer over biparametric MRI, because it has been demonstrated that in

unoptimized scans among the trial network, DCE sequences were the least-well-performed sequences,[13,22,26] whereas in PRIME the posttrial central evaluation demonstrated that DCE sequences were of high quality. Of note, a suboptimal biparametric MRI scan was not likely to be compensated for by the DCE sequences, because in most of these cases, the DCE sequences were also suboptimal (eTable 17 in Supplement 3).

Second, it is important to consider the possibility of anchoring bias underestimating significant cancer detection by multiparametric MRI, because radiologists could have been less likely to deviate from their report on the biparametric MRI when declaring their multiparametric MRI findings because they had already seen the biparametric MRI. Conversely, because clinicians were aware of the hypothesis of the study, the standard of care was multiparametric MRI prior to the trial, and the core group designing the study used DCE sequences in their daily practice, the results were more likely to have been biased in favor of multiparametric MRI detecting cancer. This is because radiologists knew that the purpose of the study was to see if areas of suspicion seen when DCE sequences were revealed harbored significant cancer; thus, they would have paid more attention to the DCE sequences than they might have in routine clinical practice and thus may have been more likely to declare a DCE sequence–specific lesion.

Third, the results reflect practice in centers with highly experienced radiologists and biopsy operators. It is therefore important to address the need for structured training and quality control in other centers. Widespread, successful implementation of biparametric MRI and targeted biopsy would be supported by educational programs and a standardized approach to reporting, potentially including formal accreditation, to ensure that diagnostic accuracy is maintained across diverse practice settings.[28-31] Such initiatives are important in aiding clinicians to interpret scans without the perceived safety net of contrast-enhanced sequences.[32]

Fourth, while a shorter scan that avoids the use of contrast, requires fewer staff to deliver, has similar clinical outcomes, and is likely to be cost-effective, a formal health economic analysis is planned and will be reported separately.

Finally, while the immediate focus must be on education and quality improvement,[13,28-31] the development of artificial intelligence tools to support image interpretation could play a significant role in augmenting the future diagnostic pathway and should be a focus of future work.[33-35]

Conclusions

This international multicenter noninferiority trial demonstrates that among experienced radiologists and provided image quality is adequate, biparametric MRI performs very similarly to multiparametric MRI for cancer detection, staging, and treatment planning. The study provides level-1 evidence that biparametric MRI could be an alternative first-line diagnostic test to multiparametric MRI for cancer diagnosis in men with suspected prostate cancer.

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