ORIGINAL ARTICLE

Temporary Health Impact of Prostate MRI and Transrectal Prostate Biopsy in Active Surveillance Prostate Cancer Patients

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Abstract

Purpose: To assess the temporary health impact of prostate multiparametric MRI (mpMRI) and transrectal prostate biopsy in an active surveillance prostate cancer population.

Methods: A two-arm institutional review board–approved HIPAA-compliant prospective observational patient-reported outcomes study was performed from November 2017 to July 2018. Inclusion criteria were men with Gleason 6 prostate cancer in active surveillance undergoing either prostate mpMRI or transrectal prostate biopsy. A survey instrument was constructed using validated metrics in consultation with the local patient- and family-centered care organization. Study subjects were recruited at the time of diagnostic testing and completed the instrument by phone 24 to 72 hours after testing. The primary outcome measure was summary testing-related quality of life (summary utility score), derived from the testing morbidities index (TMI) (scale: 0 = death and 1 = perfect health). TMI is stratified into seven domains, with each domain scored from 1 (no health impact) to 5 (extreme health impact). Testing-related quality-of-life measures in the two cohorts were compared with Mann-Whitney *U* test.

Results: In all, 122 subjects were recruited, and 90% (110 of 122 [MRI 55 of 60, biopsy 55 of 62]) successfully completed the survey instrument. The temporary quality-of-life impact of transrectal biopsy was significantly greater than that of prostate mpMRI (0.82, 95% confidence interval [CI] 0.79-0.85, versus 0.95, 95% CI 0.94-0.97; $P < .001$). The largest mean domain-level difference was for intraprocedural pain (transrectal biopsy 2.6, 95% CI 2.4-2.8, versus mpMRI 1.3, 95% CI 1.1-1.5; $P < .001$).

Conclusion: Transrectal prostate biopsy has greater temporary health impact (lower testing-related quality-of-life measure) than prostate mpMRI.

Key Words: Quality of life, patient-reported outcomes, prostate cancer, testing-related utilities, active surveillance

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INTRODUCTION

In a certain population of men with low-risk prostate cancer (Gleason 3 + 3 and some low-volume Gleason 3 + 4), active surveillance rather than active treatment is an accepted strategy for disease management [1]. In these patients, prostate biopsies are frequently performed in the confirmatory phase, approximately 6 to 12 months after initial diagnosis, with a goal of identifying otherwise occult clinically important prostate cancer (ie, Gleason score ≥ 7) [1-3]. The Michigan Urological Surgery Improvement Collaborative active surveillance road map identifies two acceptable confirmatory phase alternatives to nontargeted biopsy: prostate multiparametric MRI (mpMRI) and genomic testing [4]. Both are capable of assessing for occult clinically important prostate cancer

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and may be better tolerated by patients. However, although some quality-of-life measures have been assessed in patients with prostate cancer [5-7], to our knowledge, patient health utilities regarding prostate mpMRI and MR-ultrasound fusion biopsy have not been assessed.

Testing-related health utilities are measures of the temporary health states (and associated quality-of-life changes from baseline health) experienced by individuals during a testing experience [8-10]. The quantification of these experiences allows for formal measurement of patient preferences and comparisons of transient quality-of-life impact, between separate tests. These measures (utility states) also provide important elements for comparative effectiveness and cost-effectiveness analysis studies for evaluating alternative diagnostic and management paradigms [10].

Because the clinical and diagnostic implications of mpMRI and its role in prostate cancer detection continue to be actively studied, this investigation is aimed to determine the patient-reported experience from this test and to compare it with the patient-reported experience after transrectal prostate biopsy. The information derived may also be useful to inform modeling-based studies, such as decision tree modeling and Markov models, and trigger quality improvement initiatives. To this end, we have developed a survey instrument comprised of validated measures to assess baseline health-related and testing-related quality of life in men with Gleason 3 + 3 prostate cancer undergoing active surveillance. The purpose of this study was to assess the temporary health impact of prostate mpMRI and transrectal prostate biopsy in an active surveillance prostate cancer population.

METHODS

Institutional review board approval was obtained for this HIPAA-compliant, prospective, observational two-arm cohort study. The requirement for written informed consent was waived; verbal informed consent was obtained at the time of recruitment. STROBE criteria (ie, STrengthening the Reporting of OBservational studies in Epidemiology) were followed for manuscript development.

Study Population

Patients scheduled for prostate mpMRI or transrectal prostate biopsy (nontargeted biopsy or MR-ultrasound transrectal fusion biopsy) were prospectively screened through the electronic medical record at a large academic quaternary care medical center between November 1, 2017, and July 23, 2018. Inclusion criterion was known Gleason 3 + 3 prostate cancer diagnosed within 60 months before the upcoming diagnostic test. Exclusion criteria were prior inclusion in the study or need for general anesthesia or conscious sedation during the respective test.

The study population flow diagram is represented in Figure 1. Prospectively identified participants were recruited before their prostate mpMRI or transrectal prostate biopsy. Participants were recruited from a single hospital-based MRI suite for those within the MRI cohort (n = 60). Participants for the transrectal biopsy cohort (n = 62) were recruited from two urology clinical sites (one hospital-based and one outpatient center), staffed by four staff urologists. Verbal informed consent was obtained from the participants at the time of recruitment in accordance with Institutional Review Board guidelines. Recruited participants were considered enrolled in the study by responding to a phone interview performed 1 to 3 days after the diagnostic test was complete, to minimize recall bias (median: 1 day; interquartile range [IQR]: 1-2 days). Phone interviews were completed by a dedicated study coordinator (80.0% [88 of 110]) and by the study primary investigator (20.0% [22 of 110]). All participants enrolled in the study received a $20 participation incentive.

Questionnaire Design

A multicomponent survey questionnaire was designed using validated tools with opportunities for subjective responses. The questionnaire was refined in an iterative process in consultation with a representative of the institutional patient- and family-centered care group [11]. Validated survey instruments were not altered in verbiage or contents. The three components (in order) of the questionnaire were: (1) Short-Form 12 version 2 (SF-12); (2) testing morbidities index (TMI); (3) subjective participant responses.

SF-12 [12] is a validated baseline health-related quality-of-life survey instrument comprised of 12 questions in eight health domains. The results of this instrument are used to calculate two health outcome measures, the Physical Component Summary Score and Mental Component Summary Score [13]. Both component scores are converted to a norm-based scoring scale with a general population mean of 50 and an SD of ±10 [12]. The SF-12 is a licensed health survey copyrighted by QualityMetric Incorporated and Medical Outcomes Trust. SF-12® is a registered trademark of Medical Outcomes Trust (a part of Optum, Eden Prairie, MN).

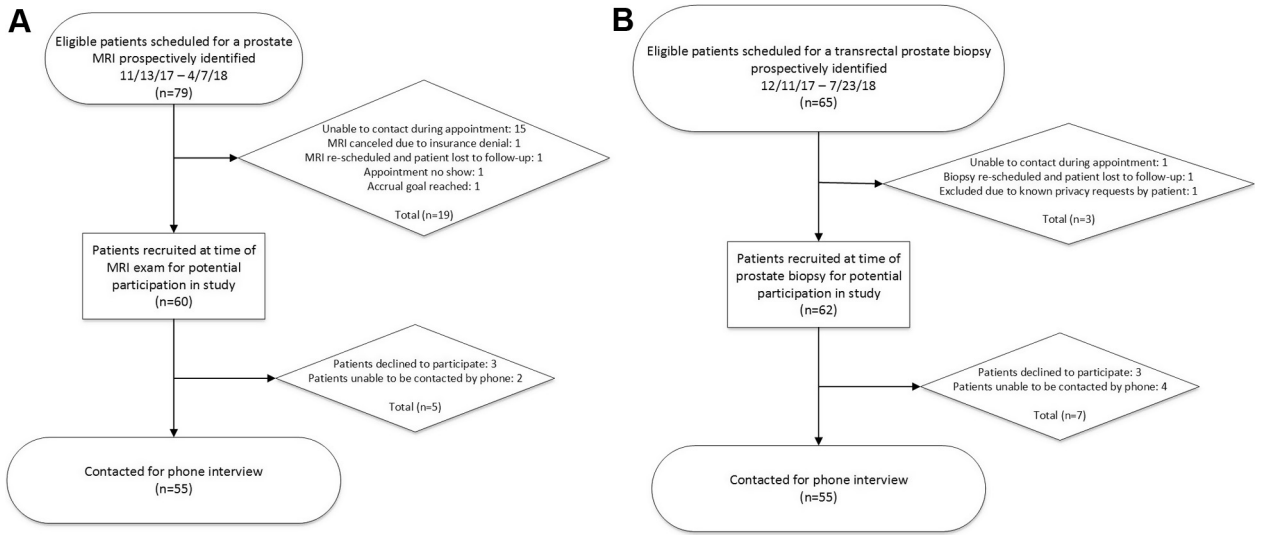

Fig 1. Study flow diagrams. Study flow for participants undergoing (A) prostate MRI and (B) transrectal prostate biopsy.

TMI [10,14,15] is a validated survey instrument designed to measure transient testing-related health utility (testing-related quality-of-life measure). The methodology and scoring of the TMI have been described previously by Swan et al [14]. The TMI measures testing-related quality of life in seven domains with seven questions (Appendix A). Domains are grouped by testing-related experiences before (pain, fear, or anxiety), during (pain, embarrassment, fear, or anxiety), and after (mental impact, physical impact) the test. Each domain is scored on a 1 to 5 scale with higher scores associated with worse experience (1 = no health impact, 2 = mild health impact, 3 = moderate health impact, 4 = severe health impact, 5 = extreme health impact). Domain scores are used to calculate a summary utility score (scale: 0-1, 0 = death and 1 = perfect health), which serves as the summary testing-related quality-of-life measure [14].

Subjective participant responses were solicited from study subjects. This component of the survey was an opportunity for participants to respond to the questions: "What was the best part of your recent test?" and "What was the worst part of your recent test?"

Additional Data Collection

Date of diagnosis of Gleason 3 + 3 prostate cancer, testing date and type, performing urologist (in the case of the prostate biopsy cohort), date of birth, and prior MRI history were obtained from the electronic medical record during prospective screening. Participant race, highest education level completed, and knowledge of testing result were obtained from the participant at the completion of the survey questionnaire. Date of survey completion was recorded after the phone interview.

Primary Outcome Measure and Sample Size. The primary outcome measure of the study is the summary testing-related quality-of-life measure (summary utility score) derived from the TMI.

An a priori power analysis was performed for the primary outcome measure based on preliminary data assessing testing-related utility scores measured by the TMI in female subjects with pelvic pain undergoing a pelvic MRI [16]. Based on these data, the utility score of a pelvic MRI was estimated at 0.81 (SD 0.16). Utilizing an alpha of 0.05, a power of 90%, and desired effect size of 0.1, this rendered a sample size of 55 participants per arm (110 total).

Data Analysis

Descriptive statistics were performed. Categorical variables are presented as percentages with raw fractions and 95% confidence intervals (CIs). Continuous data are presented as medians with IQRs. TMI measures are reported as means with 95% CIs to remain consistent with previously reported methods [10,16]. Subjective participant responses were grouped by most common themes of response and provided as raw counts as a secondary exploratory outcome.

Mann-Whitney *U* tests were performed to assess for significant differences in responses to domain-level scores and summary utility scores generated from the TMI. A Bonferroni correction was applied for the eight parameters (seven domain and one summary utility score).

Statistical significance was defined as $P < .00625$. All secondary measures were considered exploratory.

Power analysis was performed with G*Power: Statistical Power Analyses (Release 3.1.9.3) [17]. Statistical analysis was performed with SPSS software (version 24; IBM Corporation, Armonk, New York) and Microsoft Excel (version 14.0.7181.5000; Microsoft Corporation, Redmond, Washington).

RESULTS

A total of 122 participants were recruited (MRI cohort 60; biopsy cohort 62). Enrollment rates (participants contacted for the posttesting phone questionnaire) were 91.6% (55 of 60) for the MRI cohort and 88.7% (55 of 62) for the biopsy cohort (Fig. 1). All enrolled participants completed the entire questionnaire.

Demographic data for the study population are provided in Table 1. The median age of study participants was 66 years (IQR: 60-69 years). The median time from diagnosis of Gleason 3 + 3 prostate cancer to the current diagnostic testing was 119 days (IQR: 47.5-410) for the MRI cohort and 341 days (IQR: 118-531.5) for the biopsy cohort. Of the 110 participants enrolled, 91.8% (101 of

Table 1. Population demographics

Population Demographics	Total Cohort	MRI	Biopsy
Subjects	110	55	55
Median age (IQR)	66 (60-69)	66 (60.5-69.5)	65 (59-68.5)
Median days since diagnosis of prostate cancer (IQR)	248 (83-495)	119 (47.5-410)	341 (118-531.5)
MRI before current test	73.6% (81 of 110; 95% CI: 65.3%-82%)	49.1% (27 of 55; 95% CI: 35.5%-62.7%)	98.2% (54 of 55; 95% CI: 94.5%-100%)
Median days from test to survey	1 (1-2)	1 (1-2)	1 (1-2)
Aware of results at time of survey	4.5% (5 of 110; 95% CI: 0.6%-8.5%)	5.5% (3 of 55; 95% CI: 0%-11.7%)	3.6% (2 of 55; 95% CI: 0%-8.7%)
Race			
Asian	2.7% (3 of 110; 95% CI: 0%-5.8%)	3.6% (2 of 55; 95% CI: 0%-8.7%)	1.8% (1 of 55; 95% CI: 0%-5.5%)
Black or African American	5.5% (6 of 110; 95% CI: 1.1%-9.8%)	3.6% (2 of 55; 95% CI: 0%-8.7%)	7.3% (4 of 55; 95% CI: 0.2%-14.4%)
White	91.8% (101 of 110; 95% CI: 86.7%-97.0%)	92.7% (51 of 55; 95% CI: 85.6-99.8)	90.9% (50 of 55; 95% CI: 83.1%-98.8%)
Highest level of education			
Less than high school	2.7% (3 of 110; 95% CI: 0%-5.8%)	1.8% (1 of 55; 95% CI: 0%-5.5%)	3.6% (2 of 55; 95% CI: 0%-8.7%)
High school graduate	9.1% (10 of 110; 95% CI: 3.7%-14.5%)	9.1% (5 of 55; 95% CI: 1.5%-16.7%)	9.1% (5 of 55; 95% CI: 1.5%-16.7%)
Some college, no degree	20.0% (22 of 110; 95% CI: 12.5%-27.5%)	23.7% (13 of 55; 95% CI: 12.4%-34.9%)	16.3% (9 of 55; 95% CI: 6.6%-26.1%)
Associate degree (2-year college)	8.2% (9 of 110; 95% CI: 3.1%-13.3%)	9.1% (5 of 55; 95% CI: 1.5%-16.7%)	7.3% (4 of 55; 95% CI: 0.2%-14.4%)
Bachelor's degree (4-year college)	24.5% (27 of 110; 95% CI: 16.5%-32.6%)	14.5% (8 of 55; 95% CI: 5.2%-23.9%)	32.5% (19 of 55; 95% CI: 22.0%-47.1%)
Master's degree	23.6% (26 of 110; 95% CI: 15.7%-31.6%)	29.1% (16 of 55; 95% CI: 17.1%-41.1%)	18.2% (10 of 55; 95% CI: 8.0%-28.4%)
Doctoral or professional degree (PhD, MD, JD)	11.8% (13 of 110; 95% CI: 5.8%-17.9%)	12.7% (7 of 55; 95% CI: 3.9%-21.5%)	10.9% (6 of 55; 95% CI: 2.7%-19.1%)
Median SF-12 PCS (IQR)	52.7 (46.3-56.7)	52.9 (48.1-56.1)	52.2 (45.6-56.7)
Median SF-12 MCS (IQR)	57.2 (51.8-60.1)	57.6 (53.0-60.9)	57.1 (51.5-60.1)

Continuous data are summarized as medians with IQR and count data are expressed as percentages with associated raw fraction and 95% confidence intervals within parentheses. CI = confidence interval; IQR = interquartile range; MCS = Mental Component Summary Score; PCS = Physical Component Summary Score; SF-12 = Short-Form 12 version 2.

110) reported their race as "white," 5.5% (6 of 110) reported their race as "black or African American," and 2.7% (3 of 110) reported their race as "Asian." Most participants (MRI cohort 56.4% [31 of 55], biopsy cohort 63.6% [35 of 55]) reported their highest level of education to be a 4-year college degree or greater (bachelor's, master's, doctoral, or professional degree). The vast majority of the prostate biopsy cohort underwent an MR-ultrasound fusion biopsy (94.5% [52 of 55]).

Baseline health-related quality-of-life scores are summarized in Table 1. Median baseline physical health as determined by the SF-12 physical component score [12] was not significantly different between the study cohorts (mpMRI 52.9 [IQR: 48.1-56.1] versus biopsy 52.2 [IQR: 45.6-56.7]; $P = .884$) (Table 1). Median baseline mental health as determined by the SF-12 mental component score [12] was not significantly different between the study cohorts (mpMRI 57.6 [IQR: 53.0-60.9] versus biopsy 57.1 [IQR: 51.5-60.1]; $P = .311$).

Testing-related quality-of-life measures [14] are summarized in Table 2. The mean summary utility score (scale 0-1, with 0 = death and 1 = perfect health) was 0.95 (95% CI: 0.94-0.97) for the MRI cohort and 0.82 (95% CI: 0.79-0.85; $P < .0001$) for the biopsy cohort. Domain-level scores (scale 1-5, with 1 = no health impact and 5 = extreme health impact) (Table 2, Fig. 2) show the largest mean testing-related differences in fear or anxiety before the test (MRI cohort 1.4, biopsy cohort 2.1; $P < .0001$) and pain during the test (MRI cohort 1.3, biopsy cohort 2.6; $P < .0001$). Significant differences in testing-related experiences were also observed for pain before the test, embarrassment during the test, and fear or anxiety during the test (Table 2).

Participant-reported subjective responses regarding the best and worst aspects of the testing experiences are summarized in Table 3 and reported in entirety in Appendix B. For both cohorts, the most commonly reported best aspects of the testing experience were the opportunity to leave when the test was over (MRI n = 18, biopsy n = 25) and positive encounters with procedural staff (MRI n = 19, biopsy n = 11). The worst reported aspects of the MRI experience were noise during the examination (n = 11) and intravenous line placement (n = 8). The worst reported aspects of the biopsy experience were rectal probe insertion (n = 20) and procedural pain (n = 9).

Table 2. TMI domain-level scores and summary utility scores

TMI Results	MRI (n = 55)	Prostate Biopsy (n = 55)	*P* Value
Domain-level scores (1-5 scale)*			
Pain before	1.1 (95% CI: 1-1.2)	1.4 (95% CI: 1.2-1.5)	.003‡
Fear or anxiety before	1.4 (95% CI:1.2-1.5)	2.1 (95% CI:1.9-2.3)	<.0001‡
Pain during	1.3 (95% CI: 1.1-1.5)	2.6 (95% CI: 2.4-2.8)	<.0001‡
Embarrassment	1.0 (95% CI: 1-1.1)	1.6 (95% CI: 1.4-1.8)	<.0001‡
Fear or anxiety during	1.3 (95% CI: 1.1-1.4)	1.8 (95% CI: 1.6-2.1)	<.0001‡
Mental impact after	1.1 (95% CI: 1-1.2)	1.1 (95% CI: 1-1.3)	.725
Physical impact after	1.1 (95% CI: 1-1.2)	1.4 (95% CI: 1.2-1.7)	.022
Summary utility score (0-1 scale)†	0.95 (95% CI: 0.94-0.97)	0.82 (95% CI: 0.79-0.85)	<.0001‡

Data are expressed as mean scores with 95% CIs. CI = confidence interval; TMI = testing morbidities index.
*Domain-level values: 1 = no health impact, 2 = mild health impact, 3 = moderate health impact, 4 = severe health impact, 5 = extreme health impact.
†Summary utility score range: 0 = death, 1 = perfect health.
‡Statistically significant result after Bonferroni correction ($P < .00625$).

DISCUSSION

Transrectal prostate biopsy has greater temporary health impact (lower testing-related quality-of-life measure, or utility score) than prostate mpMRI. The results of this investigation allow for quantification of the degree of detriment experienced by participants during both testing experiences as well as the relative impact of the testing experiences. For active surveillance prostate cancer patients who undergo repeated rounds of confirmatory tests, these data are meaningful for incorporation into future comparative effectiveness studies and cost-effectiveness analyses. Additionally, by assessing the component utility scores of both a prostate mpMRI and a transrectal MR-ultrasound fusion biopsy, the results of this work can be used to assess component costs along the prostate mpMRI diagnostic and management continuum and may inform modeling studies, such as decision tree modeling and Markov models. Studies have been conducted to compare active surveillance to immediate treatment, but they have not used empirically collected data for health utilities of mpMRI and transrectal biopsy

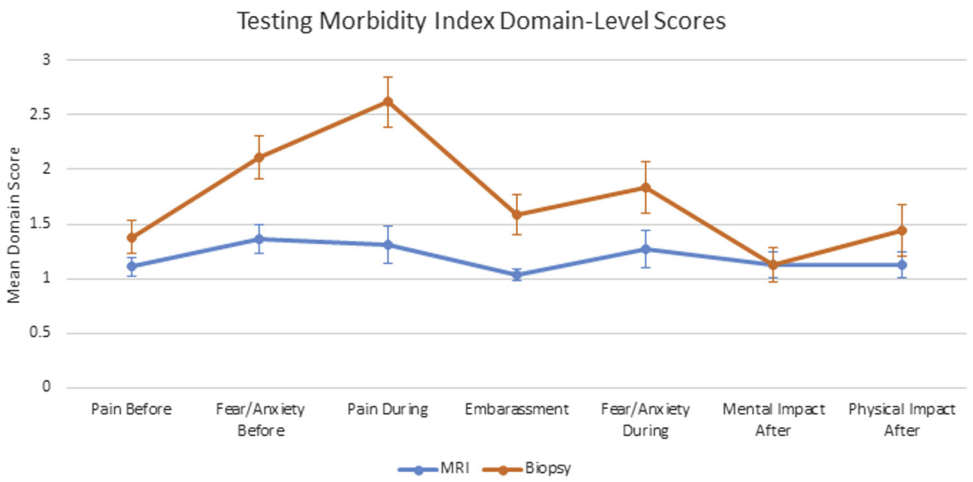

Fig 2. Mean testing morbidities index (TMI) domain scores of prostate MRI (blue) and transrectal prostate biopsy (orange). Data are summarized as means with 95% confidence intervals. Domain-level values: 1 = no health impact, 2 = mild health impact, 3 = moderate health impact, 4 = severe health impact, 5 = extreme health impact.

[18,19]. Studies that serve as sources of data on health utilities, such as that of Bremner et al [21] and Dale et al [20], have focused on overall health utilities of long-term outcomes and not the burden of procedures like mpMRI or biopsy.

Baseline physical and mental health were similar for participants undergoing prostate biopsy and MRI (Table 1), indicating that observed significant differences in testing-related temporary health experiences and quality of life were not due to latent differences in population health states (specifically, one group was not inherently more depressed or in worse physical health than the other). Multifocal domain-level differences indicated that the testing experience varied at multiple levels before and during the testing process, providing opportunities for targeted interventions aimed at improving the patient experience. In addition, subjective evaluations demonstrated that participants valued efficiency and positive staff encounters during both tests.

The TMI has been applied to various diagnostic tests with methods similar to ours. Swan et al pioneered the TMI and reported a summary utility score for screening colonoscopy of 0.88 (n = 109) and a summary utility score for breast biopsy of 0.84 (n = 100) [10,15]. Sakala et al reported the results of the TMI in women (n = 50) with pelvic pain to be 0.87 for those undergoing transvaginal ultrasound and 0.81 for those undergoing pelvic MRI [16]. Our results are similar to those reported by Swan et al, and it stands to reason that a transrectal prostate biopsy (0.82) could be viewed as having slightly greater detriment (albeit transient) than a colonoscopy or breast biopsy, due to the invasive nature, number of biopsies, and lack of sedation. Differences between utility scores reported in MRI experiences between our study

Table 3. Summary of subjective participant responses to best and worst parts of testing experiences

Best Aspects of Test (n)	Worst Aspects of Test (n)
Prostate MRI	
Staff was helpful, friendly, kind (19)	Noise (11)
Leaving, when examination was over (18)	IV placement (8)
Test was noninvasive (7)	Lying still (6)
Sleeping or relaxing during test (4)	Claustrophobia (5)
Efficiency of entire process (3)	Hunger, fasting before test (5)
Prostate biopsy	
Leaving, when examination was over (25)	Rectal probe insertion (20)
Staff was helpful, friendly, kind (11)	Procedural pain (9)
Efficiency of entire process (4)	Biopsy needles (5)
Fusion technology (watching on screen) (4)	Pain when numbing wears off (4)
Ability to determine histology (4)	Anxiety before test (4)

Top five responses in each category are presented with associated counts. Full data available in Appendix B. IV = intravenous line.

(0.95) and Sakala et al (0.81) may be due to differences in baseline pain and anxiety experienced by the respective populations and differences in willingness to undergo testing in patients with known cancer [16]. Using time trade-off (an alternative method of assessing patient preference), Grann et al reported a utility score of 0.96 for breast MRI in patients at risk for breast cancer [22]; this utility score was similar to what we observed in our MRI cohort. Kasivisvanathan et al performed a multicenter prospective study of 500 patients undergoing prostate MRI with or without fusion and nonfusion transrectal prostate biopsy and reported 24-hour posttesting quality-of-life scores measured by the European Quality of Life 5 Dimensions 5-level questionnaire [7]. Twenty-four hours after testing, they reported quality-of-life scores of 0.91 for MRI ± biopsy and 0.89 for nontargeted biopsy [7]. Differences between their measures and our results are likely due to differences in the survey instrument utilized and grouping of MRI and fusion biopsy patients into a single cohort.

Our study has limitations. A prostate mpMRI is a component of the MR-ultrasound fusion biopsy pathway and therefore the summary utility score reported for the prostate biopsy cohort could have been affected by the prior prostate MRI. We attempted to mitigate this by asking participants specifically to focus on the components of the testing experience during a short time frame before, during, and after the test. Our results also show that both tests are well tolerated in the posttesting setting (Fig. 2), suggesting that detriments from the tests are transient, and any impact from MRI is unlikely to carry over to the fusion experience. Nearly all the participants in our biopsy cohort underwent an MR-ultrasound fusion biopsy (52 of 55), which is a downstream test that follows (rather than acting as an alternative to) prostate mpMRI. This is a result of our local practice pattern serving as a major referral center for MR-ultrasound fusion biopsies. Given that the fusion experience was rated as one of the most positive components by the prostate biopsy cohort, we suspect that our measurement of the testing-related quality of life associated with a transrectal prostate biopsy would be an overestimate of a nontargeted transrectal prostate biopsy experience, albeit likely small. Our study population is a relatively small sample, largely a white college-educated population. This is a result of our local demographic and single-center experience, which could be addressed in future multicenter studies incorporating larger and more heterogeneous populations.

TAKE-HOME POINTS

- Patient-reported preference for prostate mpMRI over transrectal prostate biopsy may inform decision making for clinical indications where the diagnostic benefits of these tests are similar (eg, during the confirmatory phase of active surveillance).
- The quantified health utility scores associated with prostate mpMRI and transrectal prostate biopsy can be used to inform cost-effectiveness studies, decision tree modeling, and quality improvement initiatives.
- Subsequent studies should focus on evaluating testing-related health measures in larger and more heterogeneous populations.

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ADDITIONAL RESOURCES

Additional resources can be found online at: https://doi.org/10.1016/j.jacr.2018.11.031.

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