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Reproducibility of Multiparametric Magnetic Resonance Imaging and Fusion Guided Prostate Biopsy: Multi-Institutional External Validation by a Propensity Score Matched Cohort

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Abstract

Purpose—As the adoption of magnetic resonance imaging/ultrasound fusion guided biopsy expands, the reproducibility of outcomes at expert centers becomes essential. We sought to validate the comprehensive NCI (National Cancer Institute) experience with multiparametric magnetic resonance imaging and fusion guided biopsy in an external, independent, matched cohort of patients.

Materials and Methods—We compared 620 patients enrolled in a prospective trial comparing systematic biopsy to fusion guided biopsy at NCI to 310 who underwent a similar procedure at Long Island Jewish Medical Center. The propensity score, defined as the probability of being treated outside NCI, was calculated using the estimated logistic regression model. Patients from the hospital were matched 1:1 for age, prostate specific antigen, magnetic resonance imaging suspicion score and prior negative biopsies. Clinically significant disease was defined as Gleason 3 + 4 or greater.

Results—Before matching we found differences between the cohorts in age, magnetic resonance imaging suspicion score (each $p < 0.001$), the number of patients with prior negative biopsies ($p = 0.01$), and the overall cancer detection rate and the cancer detection rate by fusion guided biopsy (each $p < 0.001$). No difference was found in the rates of upgrading by fusion guided biopsy ($p = 0.28$) or upgrading to clinically significant disease ($p = 0.95$). A statistically significant difference remained in the overall cancer detection rate and the rate by fusion guided biopsy after matching. On subgroup analysis we found a difference in the overall cancer detection rate and the rate by fusion guided biopsy ($p < 0.001$ and 0.003) in patients with prior negative systematic biopsy but no difference in the 2 rates ($p = 0.39$ and 0.51, respectively) in biopsy naïve patients.

Conclusions—Improved detection of clinically significant cancer by magnetic resonance imaging and fusion guided biopsy is reproducible by an experienced multidisciplinary team consisting of dedicated radiologists and urologists.

Keywords

prostate; adenocarcinoma; biopsy; magnetic resonance imaging; ultrasound; high-intensity focused; transrectal

Prostate cancer is the most common noncutaneous cancer among American men with an estimated 233,000 new cases diagnosed in 2014, of which 75% represented clinically insignificant disease.[1] The recommendations of USPSTF (United States Preventive Services Task Force) gave PSA screening a grade D recommendation, finding that population based PSA screening has an unfavorable harm-to-benefit ratio and recommending against its routine use.[2] This is due to the high rate of detection of clinically insignificant disease coupled with overtreatment and subsequent morbidity with limited benefit in the long term. Conversely, a third of patients are under diagnosed by biopsy and found to have more significant disease at radical prostatectomy.[3] Such data lend support to the need for more rigorous diagnostic tools to minimize the detection of these indolent cancers while ensuring that those with lethal potential are not missed.[4]

TRUS guided biopsy of the prostate prompted by increased PSA or abnormal digital rectal examination is the current standard for prostate cancer detection. The extended sextant sampling of multiple areas of the prostate provides a systematic but nondirected approach to localized gland pathology, operating under the assumption that sampling is representative of whole gland pathology. However, it is not without limitations in that it is blind, imprecise and inefficient.[5,6] These shortcomings have spurred the search for better methods using advances in imaging, which could enable more accurate and targeted sampling of areas suspicious for cancer.[7]

MP-MRI in conjunction with MRI/US FB has emerged as a possible alternative to standard SB. FB integrates MP-MRI findings with real-time TRUS guidance, enabling the urologist to biopsy areas at increased risk for prostate cancer that are not readily apparent on TRUS alone. FB has demonstrated improved cancer detection, staging and localization, especially for clinically significant disease.[8–11] FDA (Food and Drug Administration) approval of various fusion platforms has paved the way for rapid adoption of this novel technology.[12] However, the ability of new fusion programs to replicate the promising results at expert centers is a significant concern.

The purpose of our study was to validate the results of an established high volume, tertiary referral center using fusion biopsy technology in a large cohort from a newly established program.

METHODS

We reviewed an institutional review board approved study with appropriate informed consent at NCI, NIH. Study enrollment began in August 2007 and continued through February 2014. All patients underwent baseline MP-MRI and SB. Patients with targetable lesions on MP-MRI underwent MRI/ultrasound FB with electromagnetic tracking.[13] Additionally, we reviewed an institutional review board approved study (11–322a, NCT 01566045) at LIJ from February 2012 to June 2014. Those patients underwent a procedure identical to the one described.

MP-MRI Data Acquisition

At NCI the MRI sequence parameters included triplanar T2W turbo spin-echo, diffusion-weighted MRI, axial precontrast T1-weighted MRI and axial 3-dimensional fast field echo DCE MRI. A 3 Tesla Achieva MRI device (Philips Healthcare, Cleveland, Ohio) was used in combination with a BPX-30 endorectal coil (Medrad®) tuned to 127.8 MHz and a 16-channel SENSE cardiac coil (Philips Healthcare). The balloon surrounding the coil was inflated with the perfluorocarbon Fluorinert™ Electronic Liquid PFC-770 (3 mol/l) to a volume of approximately 50 ml.[14] An effectively similar imaging protocol, cardiac coil and endorectal coil filled with PFC-770 (about 40 cc) was used at LIJ and performed at 3 Tesla using a Magnetom® Verio.[15]

For MP-MRI analysis of T2W MRI and apparent diffusion coefficient maps of diffusion weighted MRI the criterion for a visible lesion was a round ellipsoid, low signal intensity region in the prostate gland.[16] DCE MRI images were evaluated by direct visual interpretation of dynamic enhanced T1-weighted images. The diagnostic criteria for prostate cancer included a focus of asymmetrical, early and intense enhancement with rapid washout compared with the background.[16] The MP-MRI suspicion score assigned to each lesion is based on the number of positive sequences with positive T2W, diffusion-weighted, DCE-MRI and suspicion of extracapsular extension considered high suspicion.[17] Lesion scores are categorized as low, moderate and high.

MRI studies of NCI patients were reviewed by 2 experienced uroradiologists (BT and PLC) with greater than 7 years of experience. At LIJ the site leader was a fellowship trained urological oncologist (ARR) with demonstrated proficiency in MP-MRI and fusion biopsy. All patient images were reviewed by 3 of us (ARR, EB-L and RV) with 5 years of experience with prostate imaging to date and all imaging was read in consensus.

To our knowledge the work at LIJ represents the first experience in the United States outside NIH with the UroNav system (Invivo, Gainesville, Florida). All data points were recorded prospectively, including those necessary for the matched comparison.

MRI/Ultrasound FB

After MRI all patients underwent a local lidocaine nerve block, systematic TRUS 12-core biopsy and MRI/TRUS fusion guided biopsy of all suspicious lesions seen before the procedure on MP-MRI. Fusion guided biopsy was performed using the UroNav platform in conjunction with an IU-22 end-fire and a C9–5 ultrasound probe (Philips Healthcare). A minimum of 2 guided biopsy cores was obtained from each lesion seen on MP-MRI regardless of suspicion score, including 1 in the axial plane and 1 in the sagittal plane. All biopsy cores were examined by a single genitourinary pathologist from each institution (MJM and OY).

Statistical Analysis

The LIJ and NCI cohorts were compared with respect to the FB and SB outcomes. Patients with a prior positive biopsy were excluded from analysis, which resulted in a total of 930 cases, including 620 at NCI and 310 at LIJ. Outcome variables of interest included CDR,

CDR by targeted biopsy, upgrading by FB, upgrading by SB, clinically significant upgrading by FB and clinically significant upgrading by SB. Upgrading was defined as an increase in Gleason sum or primary Gleason score relative to the other biopsy modality, including cases missed by 1 biopsy modality. Clinically significant disease was defined as Gleason 3 + 4 or greater.

Propensity score matching for age, PSA, MRI suspicion score and prior negative biopsy was used to decrease bias when comparing outcome variables due to an imbalance in covariates and to simulate a randomized clinical trial. The matching procedure was implemented with the R Matching package. First, logistic regression was used to model the probability of being treated outside NCI using the covariates age, PSA, MRI suspicion score and prior negative biopsy. The propensity score, defined as the probability of being treated outside NCI, was calculated for each patient using a logistic regression model. Next patients outside NCI were matched 1:1 with patients at NCI based on the nearest neighbor match of the propensity score. When multiple matches were found, the matched data set included the multiple matched patients and the matched data were weighted to reflect the multiple matches. Matching was done for the whole cohort as well as for cancer cases only with the latter used to compare outcomes related to upgrading. Comparisons of covariates between the 2 institutions were done by the 2-sample t-test for continuous variables and the chi-square test for categorical variables. Mean differences in covariates and outcome variables were tested by the weighted t-test using the Abadie-Imbens SE. Significance was considered at $p < 0.05$.

RESULTS

The 930 patients included 620 at NCI and 310 at LIJ. Table 1 lists patient demographic characteristics. Mean age of the NCI and LIJ cohorts was 62.1 (range 36 to 81) and 65.4 years (range 40 to 79), respectively ($p < 0.001$). Mean PSA was 11.9 ng/ml at NCI and 10 ng/ml at LIJ ($p = 0.54$), demonstrating the higher risk nature of these patients. In both cohorts patients with cancer were older with higher PSA. More NCI patients presented with prior negative biopsies (68.5% vs 60%, $p = 0.01$). Subsequently more NCI patients were found to have high suspicion lesions on MRI than LIJ patients (18.4% vs 4.8%, $p < 0.001$). The CDR for combined SB and FB was 47.3% and 64.5% at NCI and LIJ, respectively. The CDR for FB alone was 40.0% at NCI and 53.2% at LIJ. A statistically significant difference between the 2 cohorts was found in the variables age, prior negative biopsies and MRI suspicion score, and in the outcome variables overall CDR and CDR by FB. There was no statistically significant difference in the percent of upgrading by FB or upgrading to clinically significant disease by FB between the populations.

The 2 patient populations were then matched 1:1 for age, PSA, MRI suspicion score and prior negative biopsy. Table 1 shows matching eliminated differences seen in age, MRI suspicion score and the percent of prior negative biopsies. The LIJ cohort had higher overall CDR (64.5% vs 47.2%, $p = 0.005$) and CDR by FB (53.2% vs 39.0%, $p < 0.001$). The LIJ cohort also showed higher rates of upgrading by FB but this difference was not significant (33.0% vs 26.1%, $p = 0.27$). Using FB the NCI and LIJ cohorts demonstrated upgrading to clinically significant disease with no significant difference (17.5% and 20%, respectively, $p = 0.6$).

To investigate the difference in overall and FB specific CDR we performed subgroup analysis of biopsy naïve patients. The 319 biopsy naïve patients included 195 from NCI and 124 from LIJ (table 2). Prior to matching these 2 populations differed in age and MRI suspicion score (each $p < 0.001$). Despite these differences there was no significant difference in FB outcomes. Both groups had similar rates of cancer detection (63.6% and 69.4%, $p = 0.35$) and CDR by FB (56.4% and 59.7%, respectively, $p = 0.65$). The rates of upgrading and upgrading to clinically significant disease were also similar ($p = 0.36$ and 0.67, respectively). Analysis of biopsy naïve patients in the matched cohort continued this trend. No significant difference was seen in any measured outcome.

We also performed subgroup analysis of patients who presented with prior negative biopsies. The 611 patients included 425 from NCI and 186 from LIJ (table 3). Before matching we found statistically significant differences in age, MRI suspicion score, and CDR overall and by FB. In the matched cohort the subgroup of patients with prior negative biopsies did not differ in age or MRI suspicion score, or in upgrading by FB or SB.

DISCUSSION

MP-MRI has shown promise in the diagnosis and staging of prostate cancer.[18,19] This modality has proven ability to identify lesions throughout the prostate that are missed by traditional SB.[20,21] The foundation of widespread adoption of FB is not only improved results compared to SB alone but also results that are consistently reproducible outside major centers with extensive experience. Studies elsewhere have not always been able to replicate the CDR achieved at expert centers with factors including experience and patient population.[22]

The strength of this study is that effectively identical MRI protocols were used. The only differences were adaptations made for the different vendors. At both sites NIH trained staff interpreted MP-MRIs and performed FBs. The differences between the 2 centers with respect to patient populations was addressed by propensity matching (table 1).

Both cohorts showed consistency with past studies in that FB was able to detect more clinically significant disease than SB with no statistically significant difference between the 2 institutions. In our study we found a difference after matching only for the outcome variables of overall CDR and CDR by FB. Subgroup analysis revealed that these differences were due to the group of patients who presented with previously negative SB. In biopsy naïve patients we found no difference in CDR or CDR by FB, leading us to conclude this patient-centric factor and not the FB system drives the differences in outcomes seen at various institutions. Unsurprisingly, we also observed higher overall CDRs and less upgrading by FB compared to the group of patients with previous negative biopsies.

The role of prostate MRI is growing to include patient selection, surveillance, staging, surgical planning and postoperative monitoring.[23–25] In this context it is important to note that our analysis emphasizes that the process, including interpreting MP-MRI and performing FB, can be duplicated at an academic medical center with a dedicated and trained multidisciplinary team of urologists and radiologists.

This study has several limitations. Subjects were enrolled at both institutions in a prospective trial comparing SB with FB. However, the subset analysis of matched patients was performed retrospectively and, thus, is subject to the inherent bias of this study design. Additionally, there is currently no nationally adopted standardized MRI suspicion scoring system.[26,27] The 2 cohorts were recoded retrospectively to use the NCI scoring system rather than PI-RADS™, version 2 because the latter was not available and the NCI cohort had already been assessed with this system. Therefore, we recommend recording granular, sequence specific data to allow for future comparisons, validation and analysis of the impact of changes in scoring systems, biopsy technology and the detection of clinically significant prostate cancer.[28] However, that may make our model and analysis difficult to apply to centers that use a different radiological suspicion scoring system. This comes at a time of increased adoption of the PI-RADS based scoring system based on the recommendations of ESUR (European Society of Urogenital Radiology).[29,30]

Furthermore, at both sites the UroNav fusion biopsy system was used. Thus, similar rates of registration and tracking errors may not be applicable to centers using different FB systems or different techniques as there is still a lack of consensus on the standard operating technique. Moreover, our methodology induced sampling bias because patients without targetable lesions seen on MRI were not considered for validation. Finally, pathological review of biopsy samples was not centralized but analyzed independently by fellowship trained genitourinary pathologists.

Followup to this study is required in a larger cohort of matched patients from multiple institutions. A larger cohort of matched patients would increase the power of this study and further emphasize our findings. Furthermore, matching by multiple institutions would enable determination of the experience needed to duplicate the outcomes achieved at these 2 centers. As broader application and validation are seen, this will give way to the use of MP-MRI in conjunction with PSA for prostate cancer screening. On this note, validation will allow for new national active surveillance guidelines that incorporate MP-MRI for followup and eliminate unnecessary biopsies.

CONCLUSIONS

The improved detection of clinically significant cancer by MP-MRI and FB is reproducible in the hands of an experienced multidisciplinary team. Our results suggest that using optimized NIH prostate MRI protocols with appropriate training in the interpretation of MP-MRI the dissemination of this technology can render equivalent outcomes.

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Abbreviations and Acronyms

CDR	cancer detection rate
DCE	dynamic contrast enhanced
FB	fusion guided biopsy
LIJ	Long Island Jewish Medical Center
MP	multiparametric
MRI	magnetic resonance imaging
NIH	National Institutes of Health
PSA	prostate specific antigen
SB	12-core systematic biopsy
T2W	T2-weighted
TRUS	transrectal ultrasound

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Table 1.

Overall patient characteristics and biopsy outcomes at vs outside NCI

	Mean Before Matching				Mean After Matching			
	NCI	**Outside**	**Difference**	**p Value**	**NCI**	**Outside**	**Difference**	**p Value**
No. pts	620	310	–	–	510	310	–	–
Age	62.1	65.4	3.2	<0.0001	65.6	65.4	−0.2	0.7328
PSA (ng/ml)	11.9	10	−1.9	0.5437	10.4	10	−0.5	0.5521
% Suspicion:				<0.0001				0.9543
Low	11	6.5	−4.5		6.2	6.5	0.3	
Moderate	70.6	88.7	18.1		89.4	88.7	−0.7	
High	18.4	4.8	−13.5		4.4	4.8	0.4	
% Prior neg biopsy	68.5	60	−8.5	0.0119	64.6	60	−4.6	0.2343
% CDR:								
By FB	40	53.2	13.2	0.0002	39.1	53.2	14.2	0.0054
By SB + FB	47.3	64.5	17.3	<0.0001	47.2	64.5	17.3	0.0004
% Upgrading:								
By FB	38.2	33	−5.2	0.2754	26.1	33	6.9	0.2701
By random biopsy	22.2	29.5	7.3	0.0832	32.3	29.5	−2.8	0.6829
Clinically significant* by FB	21.2	20.5	−0.7	0.9487	17.5	20.5	3	0.5987
Clinically significant* by SB	6.8	9.5	2.7	0.3627	14.7	9.5	−5.2	0.244

*Defined as Gleason 3 + 4 = 7 or greater.

Table 2.

Characteristics and biopsy outcomes of biopsy naïve patients at vs outside NCI

	Mean Before Matching				Mean After Matching			
	NCI	**Outside**	**Difference**	**p Value**	**NCI**	**Outside**	**Difference**	**p Value**
No. pts	195	124			139	124		
Age	61.2	65	3.8	<0.0001	65.4	65	−0.5	0.6488
PSA (ng/ml)	7.2	6.3	−0.8	0.2606	7.4	6.3	−1.1	0.1526
% Suspicion:				<0.0001				0.7668
Low	10.3	6.5	−3.8		6.7	6.5	−0.3	
Moderate	68.2	91.1	22.9		89.2	91.1	1.9	
High	21.5	2.4	−19.1		4	2.4	−1.6	
% CDR:								
By FB	56.4	59.7	3.3	0.6459	53.9	59.7	5.8	0.506
By SB + FB	63.6	69.4	5.8	0.3487	62.1	69.4	7.3	0.3922
% Upgrading:								
By FB	27.4	20.9	−6.5	0.3635	13.4	20.9	7.6	0.3429
By SB	22.6	30.2	7.7	0.277	22.1	30.2	8.1	0.4033
Clinically significant* by FB	8.9	11.6	2.8	0.6738	5.8	11.6	5.8	0.3276
Clinically significant* by SB	7.3	14	6.7	0.1749	14	14	0	1

*Defined as Gleason 3 + 4 = 7 or greater.

Table 3.

Characteristics and biopsy outcomes of patients with prior negative SB at vs outside NCI

	Mean Before Matching				Mean After Matching			
	NCI	**Outside**	**Difference**	**p Value**	**NCI**	**Outside**	**Difference**	**p Value**
No. pts	425	186			263	186		
Age	62.6	65.6	3	<0.0001	65	65.6	0.6	0.4041
PSA (ng/ml)	14.1	12.4	−1.7	0.7764	11.6	12.4	0.8	0.7566
% Suspicion:				0.0002				0.6966
Low	11.3	6.5	−4.8		7	6.5	−0.5	
Moderate	71.8	87.1	15.3		88.5	87.1	−1.4	
High	16.9	6.5	−10.5		4.5	6.5	2	
% CDR:								
By FB	32.5	48.9	16.5	0.0002	31.8	48.9	17.1	0.0029
By SB + FB	39.8	61.3	21.5	<0.0001	40.1	61.3	21.2	0.0002
% Upgrading:								
By FB	46.2	42.1	−4	0.5822	44.7	42.1	−2.6	0.7774
By SB	21.9	28.9	7.1	0.2269	28.1	28.9	0.9	0.9204
Clinically significant* by FB	30.2	27.2	−3	0.6824	29.7	27.2	−2.5	0.7706
Clinically significant* by SB	6.5	6.1	−0.4	1	14	6.1	−7.9	0.1552

*Defined as Gleason 3 + 4 = 7 or greater.