ORIGINAL RESEARCH

Comparison of MRI-ultrasound Fusion–guided and Transrectal Ultrasound–guided Prostate Biopsy for the Detection of Prostate Cancer in Biopsy-naive Men

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Objective: Transrectal ultrasound-guided prostate biopsy (TRUSPBx) is the recommended method for the histopathologic confirmation of prostate cancer. However, the overall cancer detection rate is low; hence, patients are potentially exposed to multiple biopsies and their attendant morbidity. Multiparametric MRI of the prostate followed by MRI-Ultrasound fusion-guided prostate biopsy (FBx) is an emerging diagnostic pathway that has been established and recommended in men with a persistently elevated PSA despite a previous negative biopsy. However, evidence regarding its value in the biopsy-naïve setting is scarce. The objective is to compare the diagnostic accuracy of MRI fusion-guided prostate biopsy against TRUSPBx in biopsy-naïve men.

Methods: This is a retrospective cohort study involving biopsy-naïve men with a PSA of 3 to 20 ng/ml. Primary outcomes of the study include overall cancer detection rate (CDR) and detection of clinically-significant prostate cancer (csPCa). Subgroup analyses were performed based on PSA level and prostate volume. Independent t-test, Mann Whitney U test and Chi square test were used in the statistical analysis.

Results: A total of 185 biopsy-naïve men with a PSA level of 3 – 20 ng/mL were included in the study. Median pre-biopsy PSA level was 7.07 ng/mL (5.06 – 11.0) and 9.02 ng/mL (5.8 – 13.8) in the FBx arm and TRUS-guided biopsy arm, respectively. Ninety-nine (n=99; 53%) underwent MP-MRI of the prostate followed by MRI fusion-guided prostate biopsy and eighty-six (n=86; 46%) underwent the standard TRUS-guided prostate biopsy. Compared to TRUSPBx, FBx significantly detected more prostate cancer (CDR: 68% vs 30%, p<0.0001) and csPCa (46% vs 22%, p=0.001). The diagnostic yield of FBx was distinctly superior in the subgroup of men with a PSA of 4 – 10 ng/mL (CDR: 64% vs 7%, p<0.0001; csPCa: 43% vs 2%, p<0.0001) and a prostate volume of <40grams (CDR: 82% vs 36%, p<0.0001; csPCa: 53% vs 21%, p=0.006).

Conclusion: Compared to the current standard, the diagnostic yield of MRI fusion-guided prostate biopsy is significantly better in biopsy-naïve men. FBx detected more men with prostate cancer, with a higher proportion of men having clinically-significant disease. This advantage is strongly evident in men with a PSA level of 4 – 10 ng/mL and an average prostate volume of 40 grams. Hence, Multiparametric MRI of the prostate followed by MRI fusion-guided prostate biopsy is an effective first-line diagnostic modality for prostate cancer in men presenting with elevated PSA levels.

Keywords: biopsy-naïve, fusion biopsy, prostate cancer

Introduction

Transrectal ultrasound-guided prostate biopsy (TRUSPBx) is the recommended primary method for the diagnosis of prostate cancer in men with elevated PSA levels.[1,2] However, the diagnostic proficiency of TRUSPBx has traditionally been dismal at 30 - 40% resulting to a significant false-negative rate of up to 30%.[3-6] This exposes patients to unnecessary repeat biopsy procedures as well as their attendant morbidity, which include hematuria, acute urinary retention and sepsis in up to 8 – 10% of patients.[7] Multiparametric MRI of the prostate has been demonstrated to increase the detection rate of clinically significant prostate cancer when combined with serum PSA and digital rectal examination.[8] With the integration of MRI – ultrasound fusion technology to guide prostate biopsy, the overall detection rate for prostate cancer has vastly improved, with a higher proportion of clinically significant prostate cancer detected compared to the conventional TRUSPBx.[9] However, multiparametric MRI of the prostate followed by FBx is presently not yet recommended as the primary mode of detection for prostate cancer due to paucity of evidence.[10,11] In the current study, the authors aim to determine whether multiparametric MRI-Ultrasound fusion-guided prostate biopsy (FBx) is more effective than conventional transrectal ultrasound – guided prostate biopsy in detecting prostate cancer among biopsy-naïve men.

Methods

This is a retrospective cohort study done in two tertiary hospitals in Metro Manila. The objective is to compare the efficacy of multiparametric MRI of the prostate followed by fusion guided – biopsy of the prostate against the current standard, transrectal ultrasound-guided prostate biopsy, in biopsy-naïve men (Figure 1).

Identification of the Patient Population

The records of all men who underwent a prostate biopsy in two tertiary institutions in Metro Manila were reviewed. The study population included biopsy-naïve men who underwent either the standard transrectal ultrasound-guided prostate biopsy or multiparametric MRI of the prostate followed by MRI fusion - guided prostate biopsy. The data were collected by the researcher through review of charts from January 2014 to August 2019. Included in this study were patients 40 to 85 years old, those with a pre-biopsy serum PSA of 3 – 20 ng/mL, those who underwent a transrectal ultrasound-guided prostate biopsy and those who underwent a multiparametric MRI of the prostate followed by MRI fusion - guided prostate biopsy. Patients with a PSA of >20, evidence of metastatic disease (positive bone scan or measurable visceral metastasis via CT scan or MRI), evidence of PSA elevation due to non-cancerous factors (i.e. catheterization, bladder stone, urinary tract infection, prostatitis), and a history of prostate surgery prior to the biopsy were excluded. The TRUS-guided prostate biopsy was done using a standard 8 – 10 MHz probe, with majority of the urologists adhering to a 12 to 18-core biopsy scheme. The MRI fusion-guided prostate biopsy was done transperineally, using the Koelis Trinity fusion biopsy system, and a trans-perineal prostate biopsy was performed under fusion guidance. The biopsy template was at the preference of the operating urologist.

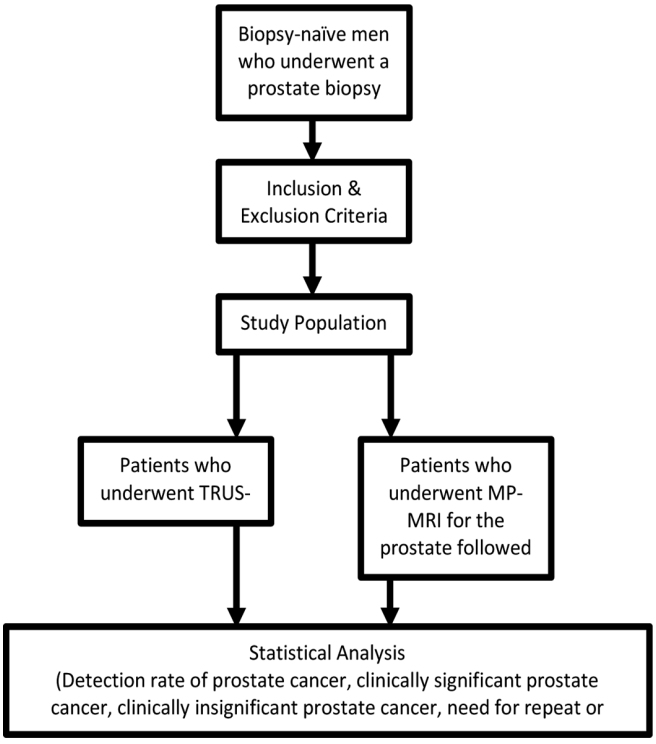

Figure 1. Schematic diagram of methodology.

Sampling Methodology

The study utilized a convenience sampling design to select study participants. G*Power 3.1.9.2 software was used to calculate the minimum sample size for the study. In the study by Van der Leest, et al (2018), detection rate of clinically-significant cancer is 23% for TRUS biopsy and 50% for MPMRI-guided fusion biopsy.[12] When alpha is set at 0.05, a total of 98 patients (49 for each group) is required to detect a significant difference with at least 80% power in clinically significant cancer detection rate between the two groups. Below is the sample size computation used in this series.

Data and Statistical Analysis

The data were encoded by the researcher in MS Excel. Stata MP version 14 software was used for data processing and analysis. Continuous data were presented as mean/standard deviation (SD) or median/ interquartile range (IQR) depending on data distribution. Categorical data were presented as frequency/percentage. Independent t-test or Mann Whitney U test was used to compare continuous data while Chi square test or Fisher's exact test was utilized for categorical data. Chi square test was performed to compare the efficacy of MPMRI fusion-guided biopsy and TRUS biopsy in detecting clinically-significant cancer. P values ≤0.05 were considered statistically significant. Charts and graphs were created using MS Excel.

Data Collection Procedure

Prior to the data collection, permission to retrieve the medical records and histopathology results was obtained from the hospital records section, ambulatory services, Department of Pathology, and the attending physician. Data collection was performed by the researcher from June 1, 2019 to August 31, 2019 using a data abstraction form. The following data were obtained from the patient charts: 1) Age, 2) Pre-biopsy PSA level, 3) Prostate weight by ultrasound or MRI, 4) Type of biopsy done, 5) Final biopsy histopathology (benign or malignant, total number of cores, total number of positive cores, core involvement), 6) Biopsy Gleasons grade group, 7) Need for repeat biopsy, 8) Definitive surgical management, 9) Final histopathologic diagnosis.

Outcome Measures

Primary outcome criteria of the study include overall cancer detection rate (CDR) and overall detection rate of clinically-significant prostate cancer. Clinically-significant prostate cancer (csPCa) is defined as biopsy proven prostate cancer with a grade group of 2 and above. The grade group is as defined by the International Society of Urological Pathology (ISUP) and as adapted by the NCCN 2019 prostate cancer guidelines version 4 (Table 1).

Z tests - Proportions: Difference between two independent proportions.

Analysis: A priori: Compute required sample size

Input:	Tail(s)=Two	Output:	Critical z=1.9599640
	Proportion p2=0.5		Sample size group 1=49
	Proportion p1=0.23		Sample size group 2=49
	α err prob =0.05		Total sample size=98
	Power (1-β err prob) =0.80		Actual power=0.8023671
	Allocation ratio N2/N1=1		

Table 1. International Society of Urological Pathology (ISUP) Grade Groups.

ISUP Grade Group	Gleasons Score	5-yr Biochemical recurrence free survival rate (%)
Grade Group I	Gleasons Score ≤ 6	94.9
Grade Group II	Gleasons Score 7 (3+4)	74.2
Grade Group III	Gleasons Score 7 (4+3)	41.0
Grade Group IV	Gleasons Score 8	55.5
Grade Group V	Gleasons Score ≥ 9	12.4

Secondary outcome criteria include detection rate of clinically insignificant prostate cancer, median core involvement, median positive cores, need for repeat or adjunct prostate biopsy (either repeat TRUS guided prostate biopsy or MRI-fusion guided prostate biopsy) and correlation of biopsy histopathology with final post-operative histopathologic diagnosis.

Ethical Considerations

This study was conducted in accordance to the accepted ethical research practices of the ICH Good Clinical Practice regulations and guidelines. Privacy and confidentiality of patient information were kept at all times. No patient identifier was collected, instead a unique study ID was assigned to each participant. Only the researcher had access to the completed data abstraction forms which were kept in a locked cabinet. Encoded data were stored in a password-protected laptop, and was only shared with the biostatistician. Data abstraction forms and encoded data will be kept for a maximum of five years from study completion. This study is investigator-initiated and not industry-funded or company-sponsored. Therefore, there is no potential conflict of interest. There are no risks for physical, psychological, social or economic harm on the subjects as a result of this retrospective study since the methodology only involves chart review. No active interventions were done and no discomfort or injury was inflicted on the study population. By establishing the effectiveness and feasibility of multiparametric MRI of the prostate followed by MRI fusion-guided prostate biopsy in the biopsy-naïve setting, the practicing urologist may now offer a more accurate, safer and effective modality, albeit at a marginally higher cost, to men suspected of having prostate cancer.

Results

Patient Data and MRI Results

After applying the inclusion and exclusion criteria, 185 patients were taken for the final analysis. Ninety-nine (n=99, 53%) patients underwent multiparametric MRI of the prostate followed by fusion-guided targeted biopsy, while eighty-six (n=86, 46%) patients underwent the conventional transrectal ultrasound-guided prostate biopsy. The median age was comparable in both groups at 66.34 ± 8.34 years for the FBx group and 67.50 ± 6.84 years for the TRUSPBx group, with more than 50% of patients at 60 – 70 years of age. Median pre-biopsy PSA levels was marginally higher in the TRUS-biopsy group at 9.02 ng/mL as compared to the FBx group at 7.07 ng/mL. With majority (58 – 69%) of patients in both arms having a serum PSA level of 3 – 10 ng/mL. Median prostate weight was also higher in the TRUS-biopsy group at 47 (IQR: 37 – 58) grams, compared to the FBx group at 36.70 (IQR: 28 – 48) grams . In the FBx arm, 39 (39.4%) patients had a maximum PI-RADs score of 3, 37 (37.3%) had a PI-RADs score of 4 and 23 (23.2%) had a PI-RADs score of 5. Table 2 illustrates the demographic and clinical profile of the patients.

MRI Fusion-guided Biopsy and TRUS-guided Biopsy Results

MRI fusion-guided biopsy was performed in 99/185 (53.5%) patients, while TRUS-guided biopsy was done in 86/185 (46.4%) of patients (Table 2). Among the 2 modalities, there is a significant difference in median core positivity, while median positive core involvement was not statistically different between the two techniques (Table 2). In the TRUS-guided biopsy arm, 9 (10.2%) patients underwent a repeat biopsy while in the MRI fusion-guided biopsy arm, none had a repeat procedure. Of the 9 patients who required a repeat biopsy, 8 patients underwent an MRI fusion-guided biopsy while 1 had a repeat TRUS-guided biopsy. Prostate cancer was eventually detected in 7/9 (77%) of them. The characteristics and outcomes of those who underwent a repeat biopsy are illustrated in Table 3.

Diagnostic Performance of MRI Fusion-guided and TRUS-guided Prostate Biopsy

The overall cancer detection rate (CDR) across both arms was 93/185 (50.2%). The overall CDR in the MRI -fusion arm is 67/99 (68%), with clinically-significant cancer detected in 46/67 (68%) of all positive biopsy results. Compared to the TRUS-guided biopsy, MRI-fusion biopsy had a significantly better overall cancer detection rate (CDR: 68% vs

Table 2. Demographic and clinical profile of patients (N=185).

Characteristics	MP MRI N=99, (%)	TRUS N=86, (%)	p value
Mean age (years) ± standard deviation	66.34 ± 8.34	67.50 ± 6.84	0.3085
Age (years)			
<60	22 (22)	10 (12)	0.095
60-70	53 (54)	46 (53)	
>70	24 (24)	30 (35)	
Median PSA* (ng/ml)	7.07 (IQR: 5.06-11)	9.02 (IQR: 5.8-13.8)	0.0395*
3-10 ng/ml	68 (69)	50 (58)	0.137
>10 ng/ml	31 (31)	36 (42)	
Median prostate weight (grams)	36.70 (IQR: 28-48)	47 (IQR: 37-58)	0.0001*
<40 grams	57 (58)	28 (33)	0.001*
≥40 grams	42 (42)	58 (67)	
Median total biopsy cores	14 (IQR: 10-17)	15 (IQR:12-16)	0.1743
PI-RADs			
3	39 (39)	-	-
4	37 (37)	-	
5	23 (23)	-	

* PSA – prostate specific antigen

Table 3. Characteristics and outcomes of patients with repeat biopsy procedures.

Px	Age	PSA	Weight	Initial H/P*	Repeat Procedure	PI-RADs	Final H/P	GG
1	72	18.4	35	Benign	MP-MRI	5	pCa	2
					Fusion	3	Atypical Glands	-
2	73	9.1	47	Benign	MP-MRI	3	pCa	4
					Fusion	4	pCa	5
3	71	20.7	24	Benign	MP-MRI	3	pCa	1
					Fusion	3	Benign	-
						3	Benign	-
4	72	8.82	37	Benign	MP-MRI	3	pCa	3
					Fusion	4	pCa	4
5	59	3.88	52	Benign	MP-MRI	4	pCa	1
					Fusion			
6	69	9.61	23	Benign	MP-MRI	5	pCa	2
					Fusion			
7	62	5.73	26	Benign	MP-MRI	3	Benign	-
					Fusion			
8	58	5.22	53	Benign	MP-MRI	3	Benign	-
					Fusion			
9	74	18.75	75	Benign	TRUS Bx	-	pCa	2

* H/P = Histopathology, pCa=Prostate cancer

30%, p<0.0001) and detection rate of clinically significant cancer (csPCa: 46% vs 22%, p=0.001). Table 4 illustrates the efficacy of MRI-fusion guided and TRUS-guided biopsy.

When stratified based on PSA levels, among patients with a pre-biopsy PSA of 4 to 10 ng/mL, MRI-Ultraound fusion-guided biopsy had a significantly better overall CDR (64% vs 7%, p<0.0001), detection rate of clinically significant cancer (43% vs 2%, p<0.0001), median core positivity (2 vs 0, p<0.00001) and need for repeat biopsy (0 vs 5 patients, p=0.011) as compared to the TRUS-guided biopsy. In those patients with a PSA 10 ng/mL or more, there was no statistical significant difference between the two groups (74% vs 61%, p=0.256). Although crudely, MRI fusion-guided biopsy had a better CDR at 74% as compared to TRUS-guided biopsy at 61%. Table 5 illustrates the sub-analysis when stratified based on pre-biopsy PSA levels.

A sub-analysis of the data set based on prostate weight was also done, subdividing the population into those with a prostate weight of less than 40 grams and those with 40 grams and above. In this cluster, MRI fusion-guided prostate biopsy had a significantly higher overall cancer detection rate in both subgroups (<40 grams: CDR 82% vs 36% p<0.0001; ≥40 grams: CDR 48% vs 28% p=0.039). It also had a significantly better detection rate of clinically significant cancer (<40 grams: csPCa 53% vs 21% p<0.006), median core positivity, median percent core involvement and need for repeat biopsy procedure in patients with a prostate of < 40 grams. Table 6 illustrates the efficacy of both groups based on prostate weight.

Under the MRI fusion-guided biopsy arm, the overall cancer detection rate is 68% with a 46% detection rate of clinically significant cancer. When stratified based on PI-RADs category, overall cancer detection rate was 35.8%, 85.2% and 87.0% for PI-RADs category 3, 4 and 5 respectively. With a detection rate of clinically significant cancer at 26%, 70% and 74% respectively (Table 7). Across both arms, 59 patients underwent definitive surgical management, 39 patients in the MRI fusion-biopsy arm and 20 patients in the TRUS-guided biopsy arm. Correlation between biopsy and post-surgery histopathology was excellent in the MRI fusion arm with all patients being positive for prostate cancer translating to a 100% accuracy rate. Furthermore, 38/39 (97.4%) patients were found to have clinically significant cancer in the final specimen. On the other hand, the TRUS-guided biopsy arm had 19 patients who had benign biopsy results but on final histopathology, 4 patients eventually turned out having prostate cancer. Table 8 illustrates the

Table 4. Efficacy of MRI fusion-guided biopsy and TRUS-guided biopsy.

Characteristics	MPMRI N=99 (%)	TRUS N=86 (%)	P Value
Overall pCa detection	67 (68)	26 (30)	<0.0001*
Overall detection of clinically-significant pCa	46 (46)	19 (22)	0.001
Ratio of overall detection of clinically-significant pCa/ pCa	68.66%	73.08%	0.5100
Positive cores, median	2 (IQR: 0-6)	0 (IQR: 0-2)	<0.0001*
Positive core involvement (%), median	90 (IQR: 60-100)	75 (IQR:50-100)	0.0611
Gleasons Grade Group			
1	21 (31)	7 (27)	0.843
2	18 (27)	5 (19)	
3	11 (16)	5 (19)	
4	12 (18)	6 (23)	
5	5 (7)	3 (12)	
Need for repeat biopsy			
Yes	0	9 (10)	0.001*
No	99 (100)	77 (90)	

GG=Gleasons Grade Group, H/P=Histopathology, pCa=Prostate Cancer

Table 5. Efficacy of MRI fusion-guided and TRUS-guided biopsy based on PSA levels.

	PSA 4-10 ng/ml			PSA >10 ng/ml		
	MPMRI, N=61, (%)	TRUS N=44, (%)	p value	MPMRI N=31, (%)	TRUS N=36, (%)	p value
Overall pCa detection	39 (64)	3 (7)	<0.0001*	23 (74)	22 (61)	0.256
Overall detection of clinically-significant pCa	26 (43)	1 (2)	<0.0001*	15 (48)	18 (50)	1.000
Ratio of overall detection of clinically significant pCa/ pCa	66.67%	33.33%	0.00007*	65.22%	81.82%	0.1218
Positive cores, median	2 (IQR: 0-5.5)	0 (IQR: 0-0)	<0.00001*	3 (IQR: 0-7)	2 (IQR: 0-7.5)	0.5424
Positive core involvement (%), median	90 (IQR: 60-100)	60 (IQR: 20-80)	0.4434	100 (IQR: 70-100)	80 (IQR: 60-100)	0.1348
Gleason score						
1	13 (33)	2 (67)	1.000	8 (35)	4 (18)	0.820
2	15 (31)	1 (33)		3 (13)	4 (18)	
3	6 (15)	0		5 (22)	5 (23)	
4	5 (13)	0		5 (22)	6 (27)	
5	3 (8)	0		2 (9)	3 (14)	
Need for repeat biopsy						
Yes	0	5 (11)	0.011*	0	3 (8)	0.243
No	61 (100)	39 (89)		31 (100)	33 (92)	

Table 6. Efficacy of MRI fusion-guided and TRUS-guided biopsy based on prostate weight.

	<40 grams			≥40 grams		
	MPMRI N=57, (%)	TRUS N=28, (%)	p value	MPMRI N=42, (%)	TRUS N=58, (%)	p value
Overall pCa detection	47 (82)	10 (36)	<0.0001*	20 (48)	16 (28)	0.039*
Overall detection of clinically significant pCa	30 (53)	6 (21)	0.006*	16 (38)	13 (22)	0.088
Ratio of overall detection of clinically significant pCa/ pCa	63.83%	60%	0.7316	80%	81.25%	0.8757
Positive cores, median	4 (IQR: 1-7)	0 (IQR: 0-2.5)	0.0003*	0 (IQR: 0-4)	0 (IQR: 0-2)	0.1118
Positive core involvement (%), median	100 (IQR: 80-100)	55 (IQR: 50-100)	0.0453*	90 (IQR: 55-100)	80 (IQR: 70-95)	0.9224
Gleason score						
1	17 (36)	4 (40)	0.521	4 (20)	3 (19)	0.983
2	15 (32)	3 (30)		3 (15)	2 (12)	
3	7 (15)	0		4 (20)	5 (31)	
4	5 (11)	1 (10)		7 (35)	5 (31)	
5	3 (6)	0		2 (10)	1 (6)	
Need for repeat biopsy						
Yes	0	5 (18)	0.003*	0	4 (7)	0.137
No	57 (100)	23 (82)		42 (100)	54 (93)	

correlation between the biopsy and post-surgery Gleasons grade group.

Discussion

Conventional transrectal ultrasound-guided prostate biopsy has been the current standard in diagnosing and risk-stratifying men suspected of having prostate cancer since it was first developed in 1989.[1,2,13] However, a number of studies have highlighted the poor diagnostic performance of this modality due to its low cancer detection rate of 30 – 40%, its significant false-negative rate of up to 30% and the inherent risk of post-procedural morbidity (e.g. gross hematuria, acute urinary retention and sepsis) in up to 10% of patients.[3,4,5,14] However, its robustness as being the initial tool of choice in diagnosing prostate cancer is not due to its diagnostic aptitude, but in fact, due to its convenience, affordability and the actual paucity of better techniques in this field of prostate cancer management.

Multiparametric MRI of the prostate is a cross-sectional imaging technique that utilizes 3 sequences to localize suspicious prostate lesions and then stratify them based on the likelihood that clinically-significant cancer exists using the PI-RADs system. With the advent of fusion technology, urologists are now able to fuse multiparametric MRI images with real-time ultrasound images to create a targeted biopsy technique with superior diagnostic proficiency. Several recent studies have already documented its advantage over traditional trans-rectal ultrasound guided prostate biopsy. Sidana, et al. (2018) compared the diagnostic yield of MRI fusion-guided prostate biopsy to the standard 12-core systematic biopsy in men with a previous negative biopsy and revealed that in the setting of a previous negative biopsy, fusion biopsy outperformed systematic biopsy in detecting clinically significant prostate cancer, 75% vs 50%. They also elaborated

Table 7. Cancer detection rate based on PI-RADs category.

PI-RADs	N	Overall Cancer Detection Rate (%)	Clinically significant pCa (%)	Clinically insignificant pCa (%)	NopCa (%)
3	39	14 (35.8)	10 (26)	4 (11)	25 (64)
4	27	23 (85.2)	19 (70)	14 (52)	4 (15)
5	23	20 (87.0)	17 (74)	3 (13)	3 (13)

Table 8. Correlation of post-biopsy and post-surgery gleasons grade.

Gleasons Group Grade MRI-Fusion Biopsy Arm (N=39)	Final Histopathologic Gleasons Grade Group					
	Benign	I	II	III	IV	V
I	-	1 (10)	6 (60)	3 (30)	-	-
II	-	-	10 (83)	2 (17)	-	-
III	-	-	3 (33)	6 (67)	-	-
IV	-	-	2 (33)	2 (33)	-	2 (33)
V	-	-	1 (33)	-	1 (33)	-
TRUS Biopsy Arm (N=20)						
	Benign	I	II	III	IV	V
Benign	15 (75)	1 (5)	1 (5)	-	2 (10)	
I	-	-	-	-	-	-
II	-	-	-	-	-	-
III	-	-	-	1 (5)	-	-
IV	-	-	-	-	-	-
V	-	-	-	-	-	-

that the diagnostic yield of fusion biopsy was not affected by the number of previous biopsies unlike in systematic biopsy wherein its yield decreased with an increasing number of previous biopsies. Woo, et al. (2019) published a meta-analysis of randomized controlled trials comparing an MRI-based pathway and a transrectal ultrasound-based pathway in the detection of clinically-significant prostate cancer. Their evidence showed that the MRI-stratified pathway detected more clinically significant prostate cancer with a relative detection rate of 1.45, 1.42 and 1.60 in all patients, biopsy-naïve and those with a prior negative biopsy, respectively.

The current status of multiparametric MRI of the prostate followed by MRI fusion-guided-prostate as the first-line diagnostic modality in evaluating prostate cancer is unclear. According to the 2019 EAU Prostate Cancer Guidelines, multiparametric MRI is only recommended in the setting of a previous negative biopsy and for patients on active surveillance.[18] Likewise, the 2017 American Urological Association guidelines on clinically localized prostate cancer have also expressed that they do not recommend multiparametric MRI of the prostate in place of systematic biopsy as the first line modality in detecting prostate cancer. They do, however, acknowledge the superior detection rate of MP-MRI and fusion-guided targeted biopsy and thus recommend it for men with a previous negative biopsy and in men with prostate cancer currently enrolled in active surveillance.[9] Fortunately, there are an increasing number of publications showing the efficacy and feasibility of multiparametric MRI and MRI fusion-guided biopsy in the biopsy-naïve setting.

The PROMIS trial evaluated the potential use of multiparametric MRI of the prostate as a triage test to determine whether men with elevated PSA levels can safely avoid immediate biopsy. According to their results, by using MP-MRI of the prostate, up to 27% of men may avoid an unnecessary biopsy, and it leads to up to 5% fewer diagnosis of clinically insignificant cancer. If the prostate biopsy was done based on the MP-MRI results, up to 18% more clinically significant prostate cancer was diagnosed as compared to the standard pathway.[19] The PRECISION trial is a multicenter, randomized, non-inferiority trial of 500 patients randomized to either standard biopsy or MP-MRI ± MRI fusion-guided biopsy.[20] Their results showed that the use of MRI before biopsy and MRI-targeted biopsy was superior to the standard TRUS-guided prostate biopsy in men at clinical risk for prostate cancer. Men who underwent MP-MRI and MRI fusion-guided biopsy had a higher detection of clinically-significant cancer and a lower detection rate of clinically-insignificant cancer.[20] Van der Leest, et al. (2019) compared an MRI-based pathway and a TRUS-guided biopsy pathway in biopsy-naïve men with PSA levels of ≥ 3ng/mL.[11] Similar to the PROMIS and PRECISION trials, their results showed that the MRI pathway enabled avoidance of immediate biopsy in up to 49% of patients due to a non-suspicious MP-MRI, and had a higher detection rate of clinically significant cancer as compared to TRUS-guided prostate biopsy.[11]

In the current series, the overall cancer detection rate of TRUS-guided prostate biopsy was 30% with a 22% detection rate of clinically-significant cancer which is comparable to recent literature.[3,4,5] In the biopsy-naïve setting, MRI fusion-guided biopsy outperformed the conventional systematic TRUS-guided biopsy in overall cancer detection at 68% vs 30%. A significantly higher number of clinically-significant cancer was also detected at 46% vs 22%. Secondary outcomes were also significantly better in the MRI fusion arm, with higher median positive cores detected, lower detection rate of clinically-insignificant prostate cancer and lower incidence of repeat biopsies. When stratified based on pre-biopsy PSA levels and prostate weight, MRI fusion-guided biopsy had a significantly better diagnostic yield in those with a PSA of 4 – 10 ng/mL (64% vs 7%) and those with a prostate weight of <40grams (82% vs 36%). In those patients with a PSA level >10ng/mL, overall cancer detection rates between both arms were statistically similar at 74% vs 61%. The accuracy of MRI fusion biopsy in determining the Gleasons group grade was also evident in the current study when biopsy specimens were correlated with the post-surgery specimens. Among the 39 patients in the MRI fusion arm who underwent definitive cancer management, 38 patients were found to have a significant Gleasons group grade of 2 and above on final histopathology. The results of the current study parallel most recently published literature and serve to affirm their findings that an MRI-based pathway followed by MRI fusion-guided biopsy is an effective

and feasible modality in detecting prostate cancer in biopsy-naïve men.

Conclusion

With a significantly better overall cancer detection rate and detection rate of clinically-significant cancer, MRI-ultrasound fusion-guided prostate biopsy is more effective as compared to the traditional TRUS-guided prostate biopsy in biopsy-naïve men. This advantage is strongly evident in those with a pre-biopsy PSA of 4 – 10 ng/mL and an average prostate weight of 40 grams. By utilizing MP-MRI of the prostate followed by MRI fusion-guided prostate biopsy as the first-line modality in prostate cancer triage, diagnostic yield is increased and unnecessary biopsies in men suspected of having prostate cancer are prudently avoided.

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