의학석사 학위논문

Is multiparametric MRI really helpful to predict upgrading and upstaging in active surveillance?

능동적 감시 대상의 전립선암 환자에서 암의 병기 상승 및 등급 상승을 예측하는 도구로서 다중 자기 공명 영상의 가치

울 산 대 학 교 대 학 원

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ABSTRACT

Background

We aimed to evaluate whether multiparametric MRI using Prostate Imaging Reporting and Data System (PI-RADS) is helpful to predict upgrading and upstaging in men with prostate cancers eligible for active surveillance.

Materials and methods

From January 2014 to December 2017, a total of 223 patients eligible for PRIAS active surveillance criteria (biopsy Gleason score ≤ 6, PSA ≤ 10, PSA density < 0.2, clinical T1c/T2, and the positive cores ≤ 2) were analyzed. All patients underwent multiparametric MRI with PI-RADS scoring and radical prostatectomy. PI-RADS scoring was performed divided into 12 zones (right/left, anterior/posterior, and base/mid/apex). 4 or 5 PI-RADS score was regarded as clinically significant cancer is likely to be present

Results

Of 223 patients, 25 (11.2%) patients had upstaging (24 patients to T3a, 1 to T3b) and 108

(48.4%) patients had upgrading (104 patients to GS 7 and 4 to GS 8-10). Patients with upgrading and upstaging tumors had older age, smaller prostate volume, higher PSA density, higher percent of positive cores, and larger tumor volume, compared to others. A total of 2676 sites from 223 patients were evaluated to identify diagnostic accuracy of PI-RADS scoring using whole mount section analysis. Overall sensitivity and specificity of PI-RADS were 36.8% and 86.5%, respectively. In multivariate analysis, PI-RADS score 4-5 lesions ≥ 2 was the independent predictor for upgrading/upstaging in patients eligible for active surveillance.

Conclusions

In this study, multiparametric MRI reported on PI-RADS scoring system has low sensitivity then previously reported, but it can be useful to detect clinically significant prostate cancer among patients on AS when there are 2 lesion or more PI-RADS 4-5 score were seen.

Keywords: prostate cancer, active surveillance, multiparametric MRI, PI-RADS

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LIST OF ABBREVIATIONS

PSA prostate specific antigen

PI-RADS Prostate Imaging Reporting and Data System

mpMRI multi-parametric magnetic resonance imaging

PPV positive predictive value

NPV negative predictive value

INTRODUCTION

Active surveillance has risen as another option for replace radical treatment of low-risk prostate cancer over past decade[1]. The new National Comprehensive Cancer Network (NCCN) guideline recommends active surveillance for very low-risk and low-risk prostate cancer groups who have 10 years or more life expectancy. The most definitive method for diagnosing prostate cancer is histological confirmation through needle biopsy. However, previous studies in this field have reported a significant discrepancy between the needle biopsy and radical prostatectomy specimens[2]. So, it is important to identify clinically significant cancer among low-risk prostate cancer.

Currently, multi-parametric magnetic resonance imaging(mpMRI) has been put to practical use to detect lymph nodes involvement and to guide prostate needle biopsy to discover significant high-risk cancer inside the prostate which is easy to can be missed with standard prostate biopsy[3,7]. But there are still controversies that MR imaging can find clinically significant prostate cancer, although it is widely used for the staging of prostate cancer.

Recent studies say that we can use magnetic-resonance imaging to identify clinically significant prostate cancer in patients on active surveillance[4], Because the ability to detect clinically significant prostate cancer has increased because of the improvement on interpretation and standardization of multi-parametric magnetic resonance imaging over past years[5,6]. Therefore, now it is established that using magnetic resonance imaging for risk assessment and magnetic resonance imaging-targeted biopsy is superior to standard risk assessment with prostate specific antigen and standard trans-rectal prostate biopsy[7]. Multi-parametric magnetic resonance imaging can be used for work-up with prostate-specific antigen(PSA), clinical staging and can provide valuable information for risk stratification of patients with localized prostate cancer[8].

In 2012, European Society of Urogenital Radiology (ESUR) designed The Prostate Imaging Reporting and Data System(PI-RADS) scoring for standardize interpretation of multiparametric magnetic resonance imaging of prostate[9]. PI-RADS system is regarded as the method to differentiate prostate cancer from normal prostate tissue. The higher the score put, the more possibility of prostate cancer present[10]. PI-RADS score is helping

clinicians to select the prostate cancer patients who is available for active surveillance, standardizing the reporting or prostate multiparametric magnetic resonance imaging[11].

In this study, we tried to clarify the ability of multiparametric prostate magnetic resonance imaging and PI-RADS scoring whether they can predict the cancer upstaging or upgrading after radical prostatectomy.

MATERIALS AND METHODS

Medical records of patients who underwent radical prostatectomy at our center from January 2014 to December 2017 for prostate cancer by 5 surgeons were reviewed retrospectively. Accordingly, 223 patients satisfying the Prostate Cancer Research International Active Surveillance(PRIAS) criteria (biopsy Gleason score(GS) $\leq$ 6, PSA $\leq$ 10, PSA density $<$ 0.2, clinical T1c/T2, and the positive cores $\leq$ 2) were included in the study. Patients who received androgen-deprivation therapy before radical prostatectomy were excluded from the study. We reviewed basal demographics, and pathologic findings, and interpretation of pre-operation multiparametric MRI of prostate.

All patients on analysis were taken multiparametric MRI of prostate after confirmed diagnosis by standard transrectal-ultrasonography guided prostate needle biopsy and before radical prostatectomy. All multiparametric MRI was performed with at least 3 sequences, including T2-weighted sequences [T2WI],

diffusion-weighted imaging [DWI], dynamic contrast-enhanced imaging [DCE]. 3 Radiologists interpreted MRI findings on PI-RADS version 2 system for 12 sections of prostate and 12 sections of extraprostatic extension. 4 or 5 PI-RADS score was regarded as clinically significant cancer is likely to be present, and PI-RADS score less than or equal to 3 was regarded as clinically significant cancer is unlikely to be present.

We defined cancer upgrading as definitive Gleason score ≥ 7, and cancer upstaging as pathological staging ≥ pathologic stage T3a. We divided patients in two groups : Some has pathologic upstaging or upgrading, Others has not. Each group was analyzed by the difference of clinical and pathologic characteristics, and whether multiparametric MRI with PI-RADS scoring and pathologic results were well correlating. Location of index tumor was also analyzed, divided as anterior/posterior and base/midgland/apex.

All 2,676 PI-RADS scored sections on MRI were evaluated to identify diagnostic

accuracy of PI-RADS scoring using whole mount section analysis. MRI characteristics for each group were examined. Comparison of pathologic findings on 12 sections and PI-RADS scored section was done for discover pathologic and imaging correlation. Pathologic results also divided in 12 sections same as PI-RADS system. We analyzed pathologic results whether a section has tumor or not, regardless of size. Overall section review, and Separative review for anterior and posterior section were done. Sensitivity, specificity, positive predictive value(PPV), negative predictive value(NPV) was considered for measure diagnostic accuracy of PI-RADS scoring system.

We sorted risk factors for cancer upgrading and upstaging that considered different by two groups, and calculated odds ratio of these risk factors for upstaging and upgrading using logistic regression analysis. We analyzed factors by both univariate and multivariate method. We used IBM SPSS Statistics software version 25.0 to perform statistical analysis. Results were regarded as significant when the p-value is under 0.05.

RESULTS

223 people who met the PRIAS criteria were analyzed. The clinical and pathologic characteristics of these patients are reported in **table 1**. The mean-age was 65.5±7.09, mean PSA was 4.6±1.63ng/dl, mean prostate volume was 43.1±17.85cc, mean PSA density was 0.116±0.04 ng/ml/cc, and mean percentage of positive core was 11.7±5.80%.

Table 1. Clinical and pathologic characteristics eligible for PRIAS criteria for AS (N=223)

Clinical characteristics	Mean ± SD
Age	65.5±7.09
PSA (ng/ml)	4.6±1.63
Prostate volume (ml)	43.1±17.85
PSA density (ng/ml/ml)	0.116±0.04
Percent of positive cores(%)	11.7±5.80
Pathologic stage	N(%)
T0	5 (2.2%)
T2	193 (86.5%)
T3a	24 (10.8%)
T3b	1 (0.5%)

N1	0
Pathologic GS	N(%)
0	5 (2.2%)
6	110 (49.3%)
3+4	82 (36.7%)
4+3	22 (9.8%)
8	3 (1.3%)
9	1 (0.5%)
Tumor volume percentage	4.3%

25 of the 223 patients had T-stage elevation on post-operation pathologic examination, 24 as T3a(tumor with extracapsular extension), and 1 as T3b(tumor invading seminal vesicle). 108 of the 223 patients has elevated Gleason score on pathology, 104 as Gleason score 7(both 3+4 and 4+3), 4 as Gleason score more than 7. Mean tumor-volume percentage were 4.3%.

When patients were classified in 2 groups depending on whether up-staging or up-grading occurred on pathologic finding or not, 110 patients has no upstaging or upgrading, and other 113 patients has upstaging or upgrading. The clinical and pathologic characteristics of each group were reported on **Table 2**. The group with upstaging or upgrading had relatively older age(63.9±7.62 vs. 67.0±6.20), smaller

prostate(47.2±19.56cc vs. 39.1±15.05cc), higher PSA density(0.111±0.04ng/ml/cc vs. 0.122±0.39ng/ml/cc), more positive biopsy core percentage(10.8±4.40% vs. 12.6±6.81%), higher tumor-volume percentage(3.0±2.28 vs. 5.5±4.62%) then other group. The PSA has no significant difference in two groups. Also, the ratio of index tumor on anterior prostate was higher(42.7% vs. 58.4%) in group with up-staging or up-grading.

Table 2. Clinical and pathologic characteristics subdivided by pathologic findings

	pT2 and GS6 (N=110)	≥pT3a or ≥ GS 7 (N=113)
Clinical characteristics	Mean ± SD	Mean ± SD
Age	63.9±7.62	67.0±6.20
PSA (ng/ml)	4.8±1.79	4.4±1.45
PSA density (ng/ml/ml)	0.111±0.04	0.122±0.39
Prostate volume (ml)	47.2±19.56	39.1±15.05
% of positive cores(%)	10.8±4.40	12.6±6.81
Tumor volume percentage(%)	3.0±2.28	5.5±4.62
Index tumor (anterior vs posterior)	N(%)	N(%)
Anterior	47 (42.7%)	66 (58.4%)
Posterior	63 (57.3%)	47 (41.6%)
Index tumor (base, midgland, apex)	N(%)	N(%)
Base	7 (6.3%)	6 (5.3%)
Midgland	52 (47.3%)	73 (64.6%)
Apex	51 (46.4%)	34 (30.1%)

2676 sections of multiparametric-MRI of prostate were reviewed with pathologic findings to survey diagnostic accuracy of PI-RADS scoring system. Overall sensitivity was 42.3%, specificity was 83.5%, PPV was 36.5%, and NPV was 86.5%. When analyzed anterior and posterior prostate separately, 42.0% of sensitivity and 87.8% specificity, 35.7% of PPV and 84.6 NPV for anterior prostate and 49.6% sensitivity and 79.3% specificity, 32.7% of PPV and 88.6% NPV for posterior prostate**(Table 3).**

Table 3. Diagnostic accuracy of PI-RADS system and MR characteristics subdivided by pathologic findings

Diagnostic accuracy of PIRADS score				
	Sensitivity(%)	Specificity(%)	PPV(%)	NPV(%)
Overall	42.3	83.5	36.8	86.5
Anterior	42.0	87.8	35.7	84.6
Posterior	49.6	79.3	32.7	88.6
MR characteristics subdivided by pathologic findings				
	pT2 and GS 6 (N=110)		≥pT3a or ≥ GS 7 (N=113)	
	N(%)		N(%)	
Presence of PI-RADS 4-5	91 (82.7)		103 (91.2)	
No. of PI-RADS 4-5				

0	16 (14.5)	10 (8.8)
1	28 (25.5)	16 (14.2)
≥2	66 (60)	87 (77.0)
Presence of PI-RADS 5	31 (28.2)	50 (44.2)
No. of PI-RADS 5		
0	79 (71.8)	63 (55.8)
1	15 (13.6)	21 (18.6)
≥2	16 (14.5)	29 (25.7)

According to results above, we presumed age, PSA, PSA density, positive-biopsy core percentage, Index tumor at anterior prostate, numbers of lesion with positive findings PIRADS as the risk factor of upstaging and upgrading for prostate cancer. Logistic regression analysis was done for reveal these suspected risk factors really affects upstaging and upgrading statistically. Univariate logistic regression showed the age(OR 1.068, 95% CI 1.026-1.112, p=0.001), PSA density over 0.1(OR 2.125, 95% CI 1.215-3.715, p=0.008), percentage of positive core(OR 1.059, 95% CI 1.005-1.116, p=0.030), index tumor at anterior prostate(OR 1.882, 95% CI 1.106-3.203, p=0.020), 2 or more PI-RADS 4 or 5 at multiparametric-MRI(OR 2.143, 95% CI 0.923-4.978, p=0.046) seems to be statistically meaningful to influence

cancer upstaging and upgrading. PSA was not statistically intentional to predict cancer upstaging and upgrading(p=0.080), and 1 lesion of PI-RADS 4-5 at multiparametric MRI does not affected cancer upstaging and upgrading(p=0.807)

Finally, multivariate logistic regression revealed that the age(OR 1.072, 95% CI 1.028-1.119, p=0.001), PSA density more than 0.10(OR 2.097, 95% CI 1.166-3.771, p=0.013), Index tumor at anterior prostate(OR 1.921, 95% CI 1.095-3.371, p=0.023), 2 or more lesions of PIRADS 4-5 score on mpMRI(OR 1.544, 95% CI 0.524-3.817, p=0.034) are the factors that impacts upstaging/upgrading of prostate cancer. Percentage of positive core was not statistically voluntary(p=0.071)

Table 4. Univariate and multivariate analysis for prediction of upgrading and upstaging

Univariate analysis	OR	95% CI	P
Age	1.068	1.026-1.112	0.001
PSA	0.863	0.731-1.018	0.080
PSA density ≥ 0.15	1.079	0.564-2.065	0.819
% of positive cores	1.059	1.005-1.116	0.030
Anterior tumor on MRI	1.874	0.728-3.446	0.683
No. lesions of PI-RADS 4-5			
0	Ref		
1	1.133	0.415–3.097	0.807

2	2.143	0.923-4.978	0.046
Multivariate analysis	OR	95% CI	P
Age	1.069	1.024-1.116	0.003
% of positive cores	1.059	1.001-1.120	0.046
No. lesions of PI-RADS 4-5			
0	Ref		
1	1.184	0.413-3.398	0.754
2	1.879	0.776-4.552	0.043

DISCUSSION

Managing patients of prostate cancer on active surveillance is on the challenge, which are avoiding delay in providing treatment to higher risk for progression and avoiding overtreatment[12]. Standard prostate biopsy and PSA has limited role in pretreatment prostate cancer risk and prognosis evaluation[13]. Comparing contemporary programs of AS, PRIAS and University of Miami protocols shows the best ability to select as many insignificant prostate cancer patients as possible with guaranteed safety[13]. The PRIAS study is the largest prospective study about AS at this time, coming close to representing a real-world situation, and its ability in selecting low-risk PCa patients is well known[14]. So, our study used PRIAS criteria for AS classification.

Need for the tool for screening the clinically insignificant prostate cancer and monitor progression on active surveillance with non-invasive method is still

present.[15]. Shoots et al, did systematic review with 19 studies, and revealed that MRI can be used in prostate cancer on active surveillance to find clinically significant disease, and it is evident that positive MRI finding can be resulted in reclassification after MRI-targeted biopsies or radical prostatectomy[4]. More recently, Klots et al did prospective multicenter trial that results MRI with targeted biopsies did not significantly increase the upgrading rate and addition of MRI imaging and targeted biopsy discovers most clinically significant diseases in men on active surveillance[16].

The American Urological Association(AUA) presents consideration of multiparametric MRI as a component for AS for localized prostate cancer patients, and European Association of Urology(EAU) proposed that imaging with multiparametric MRI has high negative-prediction value for lesion upgrading in low-risk prostate cancer patients. Siddiqui et al. represents the performance of a multiparametric MRI based nomogram can reduce repeat biopsy in AS patients[17]. And Park et al. reveals that tumor identification with multiparametric MRI can be

used as an initial management strategy because it is predictive of adverse pathologic features in localized prostate cancer patients who are eligible for AS[18].

In our study, PI-RADS showed low sensitivity in prostate cancers suitable for active surveillance criteria, as 0.423 overall, and it showed specificity of 0.835. It is relatively lower sensitivity and higher specificity, compared with recent meta-analysis that PI-RADS scoring system shows pooled sensitivity of 0.89 and specificity of 0.73[19]. The other study also showed similar results, as 0.78 of sensitivity and 0.79 of specificity[20]. However, these meta-analyzes are aimed at all of risks of prostate cancer patients, and it is different from those of this study. Kornberg Z et al. represent 41% of positive predictive value and 85% of negative predictive value for PI-RADSv2[21], which is similar with our result. And they also represent PI-RADSv2 score of 4 or 5 is associated with increased risk of biopsy upgrade.

Multiparametric-MRI is believed to be useful to identify high-grade and significant cancers[22]. Marcus et al studied the leverage of multi-parametric MRI on risk evaluation of prostate cancer, that 16.9% of patients have re-sorted to a higher risk due to MRI findings, and 8.5% of patients has been changed the therapeutic strategy[8]. And recent prospective study says standardized reported MP-MRI using PI-RADS may be a promising tool for the selection of patients suitable for AS[23]. Our study supports this concept, as resulted that existence of 2 or more lesions of PI-RADS score of 4 or 5, and 0.15 or more PSA density has strong relationships with upgrading or upstaging in prostate cancer patients fitting for AS, confirms the multiparametric MRI has notable capacity to identify clinically significant prostate cancer in patients satisfying PRIAS criteria for AS.

On the other hand, Ploussard et al. mentioned that multiparametric MRI does not make better prediction of high-risk disease in patients that are enrolled in an AS protocol according to rigid criteria[24]. Guzzo et al. demonstrated that MRI was not a significant predictor of upgrading[25]. This study had no statistical

correlation between upgrading and visible disease (PIRADS 4–5) on multiparametric MRI. We observed the better ability of multiparametric-MRI that predicts upgrading, upstaging, and unfavorable diseases.

There are studies that anterior prostate cancer has significant nature, and harder to detect by standard TRUS biopsy[26]. Lawrentschuk et al. insisted that MRI and further biopsy should be considered, because their pathology could be aggressive[27]. Song et al. said that anterior site of cancer on MRI can be expected for Gleason upgrading or unfavorable pathological outcome[28]. But our study suggests there are no statistically meaningful results that anterior location of prostate tumor on MRI is associated with upstaging and upgrading. We think that low sensitivity and PPV of PI-RADS score makes it, because there are definite evidence between pathologic results of anterior prostate tumor is associate with cancer upstaging and upgrading(HR 1.885, $p<0.001$)

Our study has several limitations. First, relatively small number of patients in

single center were enrolled; a multicenter-cohort, large pool of patients could be more probable to define the role of multiparametric MRI to seek clinically significant disease. Second, this study was not a prospective or screening trial, so our results may not be generalized to patients that has normal PSA and normal DRE findings. Third, we did not consider the interval between cancer diagnosis(biopsy-confirmed) and getting MRI images, so we could not estimate disease progression in these gaps. Fourth, 3 radiologists reviewed the MRI images, and there are doubt that reproducibility can be among radiologists.

Despite these limitations, our investigation provided interesting outcomes that can support the buildup of the role of multiparametric MRI and PI-RADS score that can be a new criterion to predict upstaging and upgrading disease.

CONCLUSION

In conclusion, this study shows multiparametric MRI reported on PI-RADS scoring system has relatively low sensitivity, but it can be useful to detect clinically significant prostate cancer among patients on AS according PRIAS criteria, based on upstaging and upgrading. We believe that multiparametric MRI has a decisive role to find clinically significant prostate cancer, with combine of other traditional serum markers and physical findings. Our results can support establishing the treatment plan of first-diagnosed prostate cancer patients.

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국문요약

우리는 Prostate Imaging Reporting and Data System (PI-RADS)을 이용한 다중 자기 공명 영상이 능동적 감시 대상의 전립선 암을 가진 남성에서 수술 후 병리 검사상 등급 상승 및 병기 상승을 예측하는 데 도움이 되는지 평가하고자 하였다

2014 년 1 월부터 2017 년까지 PRIAS 능동형 감시 기준에 해당하는 총 223 명의 환자를 분석하였다. 모든 환자는 전립선 조직 검사 후 다중 자기 공명 영상을 촬영하였으며, 이를 통해 PI-RADS 점수가 측정되다. 모든 환자는 근치적 전립선 절제술을 시행 받았다. PI-RADS 점수는 전립선 내 12 개의 구역, 전립선 외 12구역으로 나뉘어 측정되었다. 4 또는 5점이 측정된 경우 임상적으로 의미 있는 암으로 간주하였다.

223 명의 환자 중 전립선암의 병기 상승을 보인 환자가 25명이었고 등급 상승을 보인 환자는 108명이었다. 종양의 병기 상승 및 등급 상승을 보인 환자는 그렇지 않은 환자에 비해 노령이었으며, 전립선 크기가 작았으며, 전립선

특이 항원 밀도가 높았으며, 양성 코어의 비율이 높았으며 종양의 크기가 더 컸다. PI-RADS 채점의 진단 정확도를 확인하기 위해 223 명의 환자로부터 총 2676 개의 병소를 평가했다. PI-RADS 점수 시스템의 민감도와 특이도는 각각 36.8 %와 86.5 %였다. 다변량 분석에서 PI-RADS 점수 4 또는 5점인 병소가 두 군데 이상인 경우 능동적 감시 대상 환자에서 병기 상승, 등급 상승을 독립적으로 예측할 수 있었다.

본 연구에서 PI-RADS 점수 시스템을 이용한 다중 자기 공명 영상은 이전의 보고들과 같이 낮은 민감도를 가졌지만, 전립선암의 등급 상승 및 병기 상승을 예측할 수 있었다. 이 결과는 능동적 감시 대상의 전립선암 환자에서, 임상적으로 의미 있는 암을 발견하는 데에 유용하게 이용할 수 있다.