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ABDOMINAL IMAGING

ORIGINAL ARTICLE

Prospective assessment of VI-RADS score in multiparametric MRI in bladder cancer: accuracy and the factors affecting the results

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PURPOSE
We aimed to investigate the accuracy of Vesical Imaging - Reporting and Data System (VI-RADS) in the detection of muscle-invasive bladder cancer (MIBC) and to determine which factors affect the results of this scoring system.

METHODS
A prospective data analysis of 80 patients who were detected to have bladder tumor was performed between March 2019 and October 2020. VI-RADS scoring was used to determine the probability of muscle invasion. The scores were compared with pathological results to evaluate the accuracy of the VI-RADS scoring system. Interobserver agreement was assessed by VI-RADS scoring of 20 randomly chosen patients by a different experienced radiologist.

RESULTS
Using the VI-RADS scoring system, the sensitivity, specificity, positive predictive value, and negative predictive value of multiparametric magnetic resonance imaging (mpMRI) were 87.5%, 87.5%, 63.6%, and 96.6%, respectively. The interobserver agreement expressed as the interclass correlation coefficient (ICC) was 0.72 (95% CI: 0.44-0.84, $P < .001$). In addition, the flat appearance of the tumor was an important factor affecting the accuracy of the VI-RADS score (odds ratio: 5.3 [95% CI: 1.1-27.0] and relative risk: 1.87 [95% CI: 1.24-2.82]).

CONCLUSION
The mpMRI, used in conjunction with VI-RADS, has proven to be an effective imaging method for detecting muscle invasion in cases of bladder cancer. VI-RADS scoring system can distinguish whether there is a muscle-invasive and non-muscle invasive bladder cancer with acceptable accuracy. In addition, the flat appearance of the tumor is an important entity that can affect the accuracy of the VI-RADS scoring system.

Bladder cancer (BCa) is one of the most common cancers worldwide which predominantly affects men.[1] The treatment approach for BCa depends on the radiologic and pathologic stage of the tumor because muscle invasion of the tumor is one of the important parameters to decide treatment options. Preoperative radiologic staging of the muscle invasion in patients with BCa has become an important topic because the pathologic diagnosis after transurethral resection of bladder tumor (TURB) also has the potential of understaging. That is why the urologists have been performing re-TURB on patients with T1 tumors.[2]

With the use of Prostate Imaging Reporting and Data System (PI-RADS),[3,4] multiparametric magnetic resonance imaging (mpMRI) became an important tool to detect and stage solid renal masses and prostate cancer in the daily practices of urooncologists and uroradiologists. mpMRI with functional sequences (diffusion-weighted imaging and dynamic contrast-enhanced MRI) and anatomic sequences (T1 and T2) is currently the best imaging modality used in the detection of the local regional staging of bladder cancer thanks to its superior soft tissue contrast.[4] Vesical Imaging Reporting and Data System (VI-RADS) score was defined to provide preoperative BCa staging by using mpMRI and it was standardized in a number of studies.[4-10]

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The purpose of VI-RADS is to differentiate Ta-T1 non-muscle invasive bladder cancer (NMIBC) from T2-T4 muscle-invasive bladder cancer (MIBC)[5] and in accordance with this purpose, there have been few prospective studies in the literature that investigate the applicability and accuracy of the VI-RADS.

The present study aimed to investigate the impact of VI-RADS on detecting MIBC and to determine the factors that affect the results of this scoring system, prospectively.

Methods

Patients

The study was approved by the Ethics Committee of our university (KAEK-05, March 21, 2019/8). Prospective data analysis was performed for 129 patients who were detected to have bladder tumor between March 2019 and October 2020. Patients who had BCa but who could not have mpMRI due to claustrophobia (n = 1), impaired renal function (n = 1), pacemaker (n = 4), emergent intervention caused by hematoglob or gross hematuria (n = 6), unexpected tumor detected in cystoscopy performed for any reason (n = 35) or patients who had isolated diverticulum tumor (n = 1) and inadequate bladder distention (n = 1) were excluded from the study. Eighty consecutive patients with BCa who were imaged using a suitable mpMRI protocol described below before TURB were included in the study. (Figure 1). Informed consent was obtained from patients who participated in the study.

A complete TURB was performed by 5 experienced urologists using a bipolar resection system. All procedures were observed and checked by an experienced urologist in the research team to determine whether the resection technique was appropriate. The appearance of the tumors was observed in all patients. Whether the index tumors had a broad-based and flat appearance was recorded by the surgeons. Broad-based and flat-appearance tumor does not contain carcinoma in situ which cannot be corroborated by mpMRI. A second TURB was performed in patients with no muscle tissue in the specimen after initial resection or in those who had a T1 tumor according to the Tumour, Node, and Metastasis Classification System which was approved by the Union International Contre le Cancer in 2009 and updated in 2017 (8th Edn.). The median interval between MRI and the histopathological analysis was 6 (0-27) days.

Main points

- The mpMRI, used in conjunction with VI-RADS, has shown to be an effective imaging method for detecting muscle invasion in cases of bladder cancer with acceptable accuracy.
- The sensitivity, specificity, positive predictive value, and negative predictive value of mpMRI were 87.5%, 87.5%, 63.6%, and 96.6%, respectively.
- The flat appearance of the tumor is an important factor affecting the accuracy of the VI-RADS scoring system.

VI-RADS scoring was used to determine the probability of muscle invasion (Figure 2). In order to evaluate its accuracy, VI-RADS scoring system results were compared to pathological results which were reported by 2 experienced uropathologists blinded to radiologic results. mpMRI images of the patients were evaluated by an uroradiologist blinded to histopathological results of the patients under the guidance of the VI-RADS scoring system. In addition, an inter-observer agreement was also evaluated by another experienced uroradiologist.

Histopathologic assessment

All bladder tumor specimens were fixed in 10% neutral buffered formalin for 24 h, then routinely processed, paraffin-embedded tissue blocks were prepared by the Department of Pathology. All surgical specimens were sectioned transversely as a pair of 5 µm in size and the serial sections were stained with hematoxylin and eosin (H&E) before being evaluated by light microscopy. The photomicrographs, revealing the histopathologic diagnoses, were taken by 2 uropathologists, blinded to the previous images.

Imaging protocol and interpretation

mpMRI of the bladder was performed with a 1.5-T MR system (Magnetom Symphony, Siemens Medical Solutions) by using a 16-channel pelvic phased-array coil. mpMRI protocol was as follows: fast spin-echo T1-weighted images in axial with a large field-of-view (FOV), fast spin-echo T2-weighted images in axial, coronal, and sagittal planes with a small FOV, dynamic contrast-enhanced images using axial and coronal 3D gradient-echo T1-weighted VIBE (Volumetric Interpolated Breath Hold Examination) sequence (pre-contrast and post-contrast at 30 s, 90 s, and 180 s) and diffusion-weighted imaging (DWI) with multiple b-values (50-800-1400 s/mm^2) with an apparent diffusion coefficient map. Details of acquisition parameters are provided in Table 1. Patients were asked to drink 500-1000 mL of water 30 min prior to the procedure to obtain adequate bladder distension. mpMRI images of the patients were assessed by a 9-year experience board-certificated uroradiologist who was blinded to histopathological results of the patients under the guidance of the VI-RADS scoring system. In addition, a second uroradiologist with 10 years of experience conducted VI-RADS assessment of 20 randomly chosen patients in order to determine the interobserver agreement.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of mpMRI using the VI-RADS categorization system were evaluated. In addition, the impact of factors such as sex, age, primary or recurrent tumor, polypoid or flat appearance, size, and number and localization of the tumor on the VI-RADS scoring system was determined for the first time in the literature.

Statistical analysis

Statistical analyses were performed with MedCalc (MedCalc Software) program. Continuous variables were shown as mean ± standard deviation. Categorical variables were compared by Fisher's exact test. Statistical comparisons of 2 groups were performed with the Student's t test. The diagnostic performance of MRI VI-RADS scoring was evaluated by receiver operating characteristics (ROC) analysis. Sensitivity, specificity, PPV, NPV, and likelihood ratio values were calculated with 2 × 2 contingency tables for the determined cutoff values. Youden's index (J) was used to capture the performance of the diagnostic test in a single statistic.

The interclass correlation coefficient (ICC) between the 2 radiologists was also evaluated. The correlation was classified as poor (ICC < 0.40), fair to good (ICC = 0.40-0.75), or excellent (ICC > 0.75). A *P*-value of less than .05 was considered statistically significant.

Results

The study population consisted of 80 patients including 68 men (85%) and 12 women (15%) with a mean age of 71 ± 11 years. According to the pathological results, 16 patients (20%) had MIBC and 64

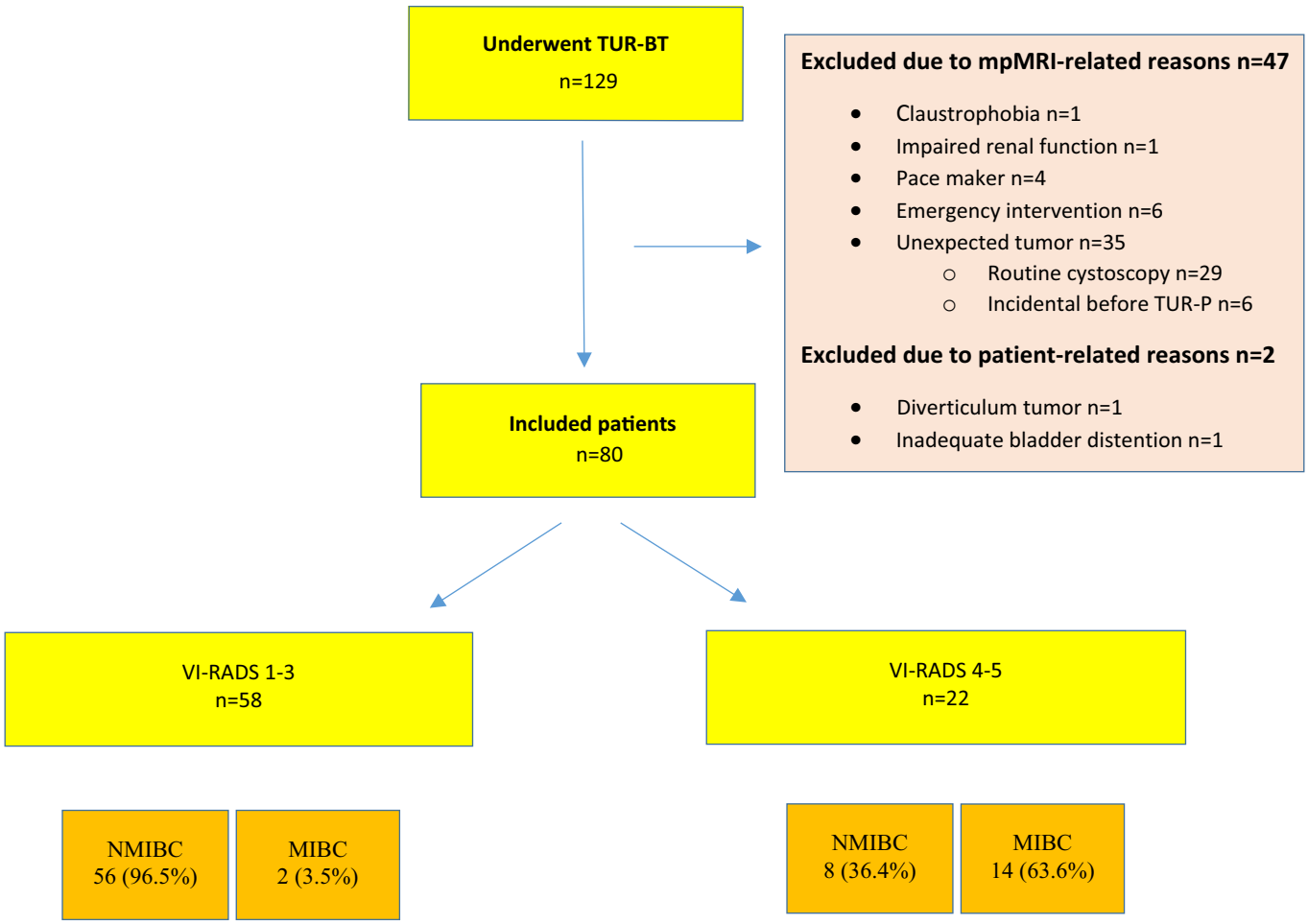


Figure 1. Study flow chart. TUR-BT, transurethral resection of bladder tumor; mpMRI, multiparametric magnetic resonance imaging; TUR-P, transurethral resection of prostate; VI-RADS, Vesical Imaging - Reporting and Data System; MIBC, muscle-invasive bladder cancer; non-muscle-invasive bladder cancer.

patients (80%) had NMIBC. The tumor was primary in 65 patients (81.3%) and recurrent in 15 patients (18.7%). While the tumor diameter was less than 3 cm in 34 patients (42.5%), the remaining 46 patients (57.5%) had a tumor larger than 3 cm. We used a cutoff value of 3 cm for the tumor diameter because according to the European Association of Urology Guidelines on bladder cancer in 2020, bladder tumors larger than 3 cm have a greater risk for progression and recurrence.[11] Thirty-nine patients had a single tumor, 17 patients had 2 lesions, and 24 patients had multiple (≥3) tumors. While 38 of the patients had broad-based and flat-tumor appearance of index lesion with or without other stalk tumors, 42 patients did not have any tumor component including broad-based tumor appearance and they had only polypoid and stalk appearance tumors. mpMRI made the correct histopathological staging in 70 patients (87.5%); 8 cases (10%) were over staged and 2 cases (2.5%) were understaged. Seventy-nine of the patients included in the study had transitional cell carcinomas and 1 patient had papillary urothelial neoplasm of low malignant potential.

The distribution of VI-RADS score percentages according to histopathological stages was presented in Table 2. When the cutoff VI-RADS score ≥4 was used to describe MIBC, the area under the curve (AUC) was calculated as 0.924 (95% CI: 0.842-0.971, standard error: 0.035, $P < .001$) according to histopathological stages with ROC analysis (Figure 3) and the sensitivity, specificity, PPV, and NPV of mpMRI using VI-RADS categorization were 87.5%, 87.5%, 63.6%, and 96.6%, respectively (Table 3). The interobserver agreement expressed as the ICC was 0.72 (95% CI: 0.44-0.84, $P < .001$).

As for the secondary outcome, the flat appearance of the tumor is found to be the only factor affecting the accuracy of the VI-RADS score. The odds ratio and relative risk for the relationship between the flat appearance of the tumor and the discordance of VI-RADS scoring and histopathological staging were 5.3 (95% CI: 1.1-27.0) and 1.87 (95% CI: 1.24-2.82), respectively. Eighty percent of the patients with discordant MRI VI-RADS scoring and histopathological staging results had flat- and broad-based-appearance tumor and they were more prone to be overstaged (75%).

Discussion

BCa is a multifaceted cancer and has the potential to become an aggressive tumor in a short period. The treatment approach of the BCa depends on the radiologic and pathologic stage of the tumor. Thus, preoperative radiological staging of BCa has become an important issue. Due to its superior soft tissue, contrast mpMRI was described to detect prostate cancer by using PI-RADS in urooncology.[4] mpMRI, by its ability to differentiate bladder wall layers, has been subsequently described as an important imaging modality for local

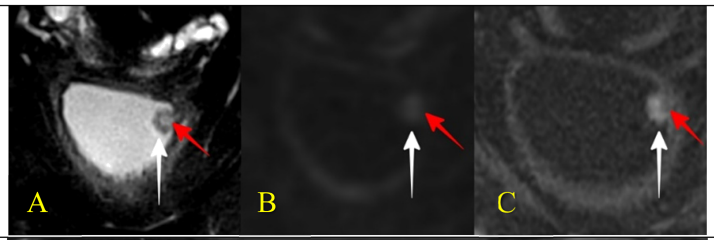
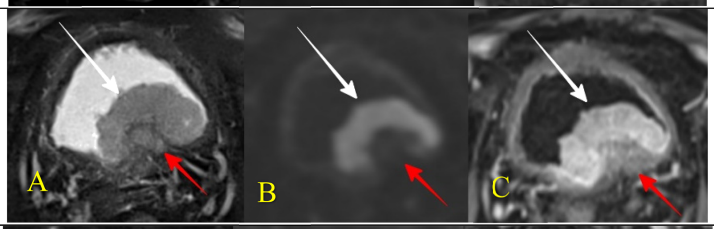
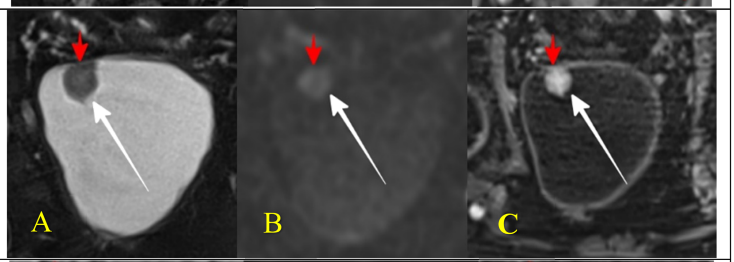
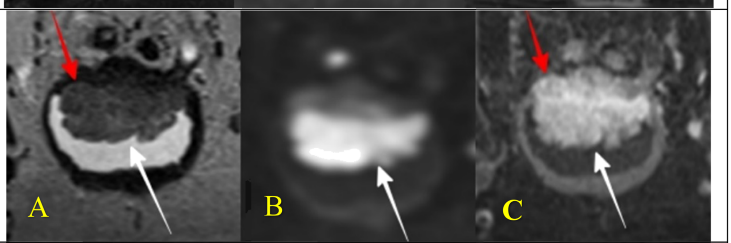
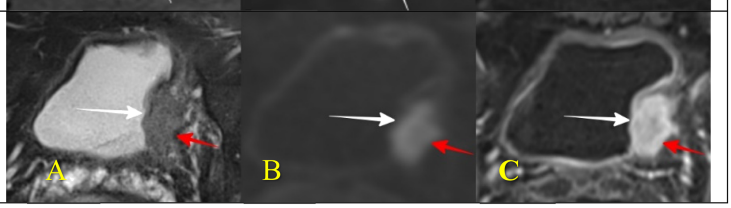
VI-RADS Score	Definition	T2WI (SC)	DWI and CE	
1	Muscle invasion is highly unlikely	SC-1	DWI and CE-1	
2	Muscle invasion is unlikely to be present	SC-2,3	DWI and/or CE-2	
3	Muscle invasion is equivocal	SC-3	DWI and CE-3	
4	Muscle invasion is likely	SC-3, 4, 5	DWI and/or CE-4	
5	Invasion of muscle and beyond the bladder is very likely	SC-4, 5	DWI and/or CE-5	

Figure 2. mpMRI VI-RADS classification according to T2WI, DWI, and DCE-MRI. mpMRI, multiparametric magnetic resonance imaging; VI-RADS, Vesical Imaging Reporting and Data System; T2WI, T2-weighted images; DWI, diffusion-weighted imaging; DCE-MRI, dynamic contrast-enhanced magnetic resonance imaging.

Table 1. Acquisition parameters of the mpMRI

Sequence parameters	Large FOV unenhanced T1WI	Multiplanar T2WI	Diffusion-weighted images	Multiphase contrast-enhanced T1WI
Plane	A	A, C, S	A, S	S and C or A
FOV (cm)	28-36	20-24	20-24	20-24
Slice thickness/gap	5-7/1	4/1-2	4/0-1	4/-2 or 3/-1.5
TR/TE	500-800/7-10 400-650/8-10	3500/102 3500-4000/102	6000/60-66 3500-6000/62-96	3.9-5.3/1.9-2.1 3.6-4.5/1.4-2.1
Flip angle	90	90	90	15
NEX	2	3	6	1
Matrix	448 × 224	320 × 224	128 × 128	256 × 128-160 320 × 192

FOV, field-of-view; T2WI, T2-weighted images; T1WI, T1-weighted images.

Table 2. Distribution of VI-RADS score percentages according to histopathological stages

		Non-muscle invasive (n = 64)	Muscle invasive (n = 16)
VI-RADS scores according to mpMRI	VI-RADS 1, n (%)	1 (1.6%)	0
	VI-RADS 2, n (%)	26 (40.6%)	0
	VI-RADS 3, n (%)	29 (45.3%)	2 (12.5%)
	VI-RADS 4, n (%)	5 (7.8%)	3 (18.8%)
	VI-RADS 5, n (%)	3 (4.7%)	11 (68.8%)

VI-RADS, Vesical Imaging Reporting and Data System; mpMRI, multiparametric magnetic resonance imaging.

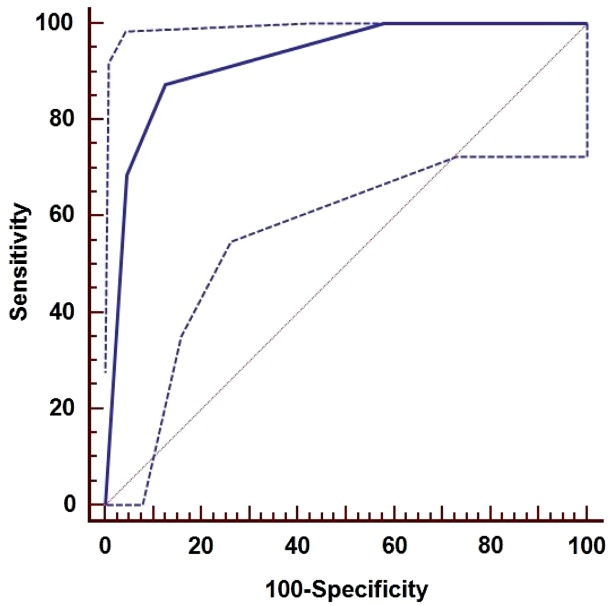


Figure 3. ROC curve for MRI VI-RADS phases according to histopathological stages (95% CI of the curve shown in dashed lines). ROC, receiver operating characteristics; MRI, magnetic resonance imaging; VI-RADS, Vesical Imaging Reporting and Data System.

staging of BCa using VI-RADS scoring system recently.[1,5]

After Panebianco et al.[5] described the VI-RADS score for BCa at the end of 2018, Barchetti et al.[6] published a retrospective study with 78 patients in October 2019. When they defined cutoff VI-RADS value ≥4 for muscle invasion, sensitivity and specificity were extremely high (82% and 94% for the first radiologist; 77% and 89% for the second radiologist). According to their results, PPV and NPV values were 86% and 93% for the first radiologist and 74% and 91% for the second radiologist, respectively. Uneo et al.[7] reported that 93%-94% of patients who scored as VI-RADS 4 and 5 had muscle invasion and there was no muscle invasion in any of patients scored as VI-RADS 1.

Makboul et al.[8] published the first prospective study investigating the accuracy of the VI-RADS application in MIBC at the end of 2019. They evaluated 50 patients and VI-RADS score predicted muscle invasion in 84% of the patients. The sensitivity and specificity of VI-RADS scores of their results were 78% and 88%, respectively, similar to our results and AUC was 0.83 which is slightly lower than our result.

Followed by Makboul et al.,[8] Del Giudice et al.[9] published the second prospective study on this topic at the beginning of 2020 with the sensitivity, specificity, PPV, and NPV of VI-RADS scores of 91.9%, 91.1%, 77.5%, and 97.1%, respectively. In addition, they presented that sensitivity, specificity, PPV, and NPV were 85%, 93.6%, 74.5%, and 96.6%, respectively, in patients who underwent re-TURB prior to the second resection. However, they defined cut-off VI-RADS value ≥3 for muscle invasion, unlike the literature.

Marchioni et al.[10] has investigated a total of 68 lesions in 38 patients prospectively by mpMRI. Only 7 (10.3%) of the lesions were MIBC and the VI-RADS scoring system had high sensitivity and specificity similar to the literature (Table 5). In addition, Del Giudice et al.[12] also demonstrated that the VI-RADS score has high sensitivity and specificity (90.2% and 98.1%, respectively) to detect extravesical urothelial cancer.

Woo et al.[13] published the first meta-analysis to evaluate the diagnostic value of VI-RADS for the prediction of muscle invasion in bladder cancer recently.

Table 3. Diagnostic evaluation of VI-RADS score according to histopathological stages

		NMIBC (n = 64)	MIBC (n = 16)	AUC (95% CI)	Youden's index (J)	Sensitivity	Specificity	PPV	NPV
MRI VI-RADS Score	(1 + 2 + 3) n (4 + 5) n	56 8	2 14	0.924 (0.842-0.971)	0.750	87.5%	87.5%	63%.6	96.6%
MRI VI-RADS Score	(1 + 2) n (3 + 4 + 5) n	27 37	0 16	0.924 (0.842-0.971)	0.422	100%	42.2%	30.2%	100%
MRI VI-RADS Score	(1+2) n (4+5) n	27 8	0 14	0.933 (0.864-1.000)	0.771	100%	77.1%	63.6%	100%

AUC values were determined by ROC analysis.
Youden's index (J) formula = sensitivity − (1 − specificity).
NMIBC, non-muscle-invasive bladder cancer; MIBC, muscle-invasive bladder cancer; AUC, area under the curve; PPV, positive predictive value; NNV, negative predictive value; MRI, magnetic resonance imaging; VI-RADS, Vesical Imaging Reporting and Data System.

Table 4. Evaluation of demographic and tumor characteristics of cases with and without compatible MRI VI-RADS scoring and histopathological staging results

	Compatible group (n = 70)	Non-compatible group (n = 10)	*P*
Age, year	70.7 ± 10.7	70.4 ± 10.5	.928[a]
Sex, M/F	58/12	10/0	.345[b]
Primary/recurrence Primary, n (%) Recurrence, n (%)	56 (80.0%) 14 (20.0%)	9 (90.0%) 1 (10.0%)	.678[b]
Flat appearance tumor Absent, n (%) Existent, n (%)	40 (57.1%) 30 (42.9%)	2 (20.0%) 8 (80.0%)	.041[b]
Number of the tumor n = 1, n (%) > n = 1, n (%)	32 (45.7%) 38 (54.3%)	7 (70.0%) 3 (30.0%)	.188[b]
Size of the tumor <3 cm, n (%) >3 cm, n (%)	32 (45.7%) 38 (54.3%)	2 (20.0%) 8 (80.0%)	.177[b]
Tumor in the trigon Absent, n (%) Existent, n (%)	53 (75.7%) 17 (24.3%)	6 (60.0%) 4 (40.0%)	.442[b]
Grade Low grade, n (%) High grade, n (%)	36 (51.4%) 34 (48.6%)	3 (30.0%) 7 (70.0%)	.313[b]

[a]*P* value was calculated using the Student t test.
[b]*P* value was calculated using Fisher exact test.

They included 6 studies with a total of 1770 patients. According to their results, pooled sensitivity, specificity, and the AUC were 0.83, 0.90, and 0.94, respectively.[13] Another recent meta-analysis includes 6 studies with 1064 patients that demonstrated that the pooled sensitivity and specificity were 0.90 and 0.86, respectively.[14]

The current study determined the sensitivity, specificity, PPV, and NPV of mpMRI using VI-RADS categorization as 87.5%, 87.5%, 63.6%, and 96.6%, respectively. The results of the current study are compatible with the literature (Table 4 and Table 5).

The second aim of the present study was to identify the predictive factors which might affect the accuracy of the mpMRI. Thus, prospective factors such as sex, age, primary or recurrent tumor, accompanying tumors with a flat appearance, size, and the number and localization of the tumor were investigated for the first time in the present study. The tumors with a flat appearance were more prone to report false VI-RADS score according to our results and in the presence of a flat appearance, the probability of discordant VI-RADS results was 1.87 times higher. In addition, when compared with pathology results, 8 cases were graded as overstaged and 2 cases as understaged in mpMRI examination and tumors with flat and broad-based appearance were more prone to be overstaged (75%). The pathologic diagnosis after TURB has a potential for understaging. In our study, 80% of incorrect staging arose from lesions larger than 3.0 cm. Lesions with a larger diameter than 3 cm may have extended outside of the bladder and may have an higher stage on mpMRI than the pathological result. As known, an actual and correct staging of T4 bladder cancer requires cystectomic evaluation. This situation may be attributed to the disadvantage of TURB procedure than VIRADS categorization.

The clear separation between cancer and bladder wall is quite important for VI-RADS classification of urinary bladder cancer on mpMRI. DWI of stalks shows low signal intensity because stalks extending from the bladder wall into the tumor consist of fibrotic tissues and mild inflammatory cell infiltration. Saito et al. reported that T2-weighted imaging is the best sequence for detecting stalks.[15] These 2 important sequences of

Table 5. Results of prospective studies in literature and our own series

Literature	Design	Case number	MIBC definition (VI-RADS)	Sensitivity, %	Specificity, %	PPV,%	NPV, %	Pooled accuracy (AUC)	Interreader agreement
Makboul et al[8]	Prospective	50	NA	78	88	78	88	0.83	0.87
Del Giudice et al[9]	Prospective	231	≥3	91.9	91.1	77.5	97.1	0.94	0.81
Marchioni et al[10]	Prospective	38	≥4	85.7	86.9	NA	NA	0.93	0.76
Our study	Prospective	80	≥4	87.5	87.5	63.6	96.6	0.92	0.72

MIBC, muscle-invasive bladder cancer; VI-RADS, Vesical Imaging Reporting and Data System; PPV, positive predictive value; NNV, negative predictive value; AUC, area under the curve.

VI-RADS categorization make separation of tumor and bladder wall easy for radiologists. As a result, there is higher accuracy of VI-RADS 1-2 categorization on bladder cancer with stalk. This can be attributed to bladder tumors with stalks having a tendency to be low grades and stages compared with villous tumors and imaging characteristics of these lesions. This situation explains the increase in the error rate in the flat lesions detected in our study.

Despite promising outcomes, we acknowledge that our study has some limitations. First, although the study was designed prospectively, the results were obtained with a relatively small-sized sample due to the COVID-19 pandemic which affected the health system and routine functioning worldwide. Second, we performed the TURB procedure and cystectomic evaluation of patients may give more accurate results. Although there is no disadvantage in the literature regarding a 1.5 T MRI scanner, the visibility of flat lesions may be better in high-field scanners. There is a need for future studies on this subject.

Finally, despite the limitations of the present study, using the VI-RADS score with the rapidly developing technology to evaluate muscle invasion of the BCa is found to be promising. In the light of the present study, mpMRI will make urologists more cautious in interpreting the pathological results of TURB. The effect of the flat appearance of a bladder tumor on the VI-RADS scoring system needs to be solved in the future with the developing technology.

In conclusion, the mpMRI, used in conjunction with VI-RADS, has shown to be an effective imaging method for detecting muscle invasion in cases of BCa. VI-RADS scoring system can distinguish whether there is a MIBC and NMIBC with acceptable accuracy. In addition, the present study identified that the flat appearance of the tumor is an important factor affecting the accuracy of the VI-RADS scoring system.

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Conflict of interest disclosure

The authors declared no conflicts of interest.

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