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Original Article

Evaluating the concordance between Vesical Imaging Reporting and Data System scores and bladder tumor histopathology

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Abstract *Objective:* This study aimed to assess the local staging of bladder tumors in patients utilizing preoperative multiparametric MRI (mpMRI) and to demonstrate the clinical efficacy of this method through a comparative analysis with corresponding histopathological findings.

Methods: Between November 2020 and April 2022, 63 patients with a planned cystoscopy and a preliminary or previous diagnosis of bladder tumor were included. All participants underwent mpMRI, and Vesical Imaging Reporting and Data System (VI-RADS) criteria were applied to assess the recorded images. Subsequently, obtained biopsies were histopathologically examined and compared with radiological findings.

Results: Of the 63 participants, 60 were male, and three were female. Categorizing tumors with a VI-RADS score of >3 as muscle invasive, 84% were radiologically classified as having an invasive bladder tumor. However, histopathological results indicated invasive bladder tumors in 52% of cases. Sensitivity of the VI-RADS score was 100%; specificity was 23%; the negative predictive value was 100%; and the positive predictive value was 62%.

Conclusion: The scoring system obtained through mpMRI, VI-RADS, proves to be a successful method, particularly in determining the absence of muscle invasion in bladder cancer. Its efficacy in detecting muscle invasion in bladder tumors could be further enhanced with additional studies, suggesting potential for increased diagnostic efficiency through ongoing research. The VI-RADS could enhance the selection of patients eligible for accurate diagnosis and treatment.

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1. Introduction

Bladder cancer, characterized by its prevalence, substantial treatment costs, and high morbidity and mortality rates, underscores the critical importance of early diagnosis, accurate staging, and optimal treatment planning [1]. The clinical staging of tumors, particularly the T stage, plays a pivotal role in guiding the treatment trajectory for bladder cancer. Clinical, radiological, and histopathological interpretations contribute to understanding the pathological stage of patients. However, notable disparities exist between pathological staging results and clinical staging outcomes, encompassing physical examination, biopsy, and imaging [2].

Achieving the precise staging for bladder cancer necessitates a comprehensive evaluation of clinical, radiological, and histopathological findings. Failures in obtaining sufficient data, particularly in assessing muscle invasion during transurethral surgery, can result in delayed diagnoses and potential disease progression. Consequently, the significance of the accurate preoperative staging is escalating. To optimize the preoperative staging and treatment strategies for bladder tumors, the integration of advanced imaging devices becomes imperative [3].

The conventional diagnostic approach relies on clinical examination, cystoscopy, and transurethral resection of bladder tumor (TURBT) to confirm the histopathological diagnosis and muscle invasiveness. CT is usually used for the evaluation of locally advanced disease, N- and M-stage [4,5]. The precise staging is crucial as the prognosis and management of bladder cancer patients heavily rely on the local tumor stage and the presence of lymph node or distant metastases [4,6]. However, there exists a significant disparity between the preoperative clinical staging (including combined bimanual examination, TURBT, and conventional imaging) and final pathological staging based on radical cystectomy and lymph node dissection, with an inaccuracy rate ranging from 23% to 50%. This discrepancy is mainly attributed to the understaging of both the depth of local invasion and lymph node metastatic involvement [7,8]. MRI emerges as a highly effective modality for predicting the local staging of bladder cancer, surpassing other methods in efficacy. The advent of multiparametric MRI (mpMRI) further enhances the ability to evaluate the invasion status of tumors, providing valuable insights into disease progression [6].

In 2018, Panebianco et al. [6] introduced the Vesical Imaging Reporting and Data System (VI-RADS) score. Designed to evaluate T2-weighted (T2W), dynamic contrast-enhanced (DCE), and diffusion-weighted imaging (DWI) sequences obtained through mpMRI, the VI-RADS aims to standardize these results for determining the degree of invasion of bladder tumors. The scoring system categorizes the invasion probability into five distinct classes: VI-RADS 1 (very low probability), VI-RADS 2 (low probability), VI-RADS 3 (uncertain probability), VI-RADS 4 (probable invasion), and VI-RADS 5

(presence of invasion, with the tumor reaching the serosa) [6].

VI-RADS scores are derived from the evaluation of bladder tumors using mpMRI, incorporating histopathological results to enhance accuracy in determining invasion status.

2. Patients and methods

This prospective study was conducted with the approval of the Inonu University of Clinical Research and Publication Ethics Committee under the protocol code 2020/162. The informed consent was obtained from all participating patients before the procedures to be performed in the study.

Between November 2020 and April 2022, 80 patients who were scheduled for cystoscopy due to suspected bladder tumors and could not achieve complete resection with TURBT were referred to the Department of Radiology for mpMRI before the relevant surgical procedures. Exclusion criteria included patients with renal insufficiency (glomerular filtration rate of <60 mL/min/1.73 m²; $n=4$), metal implants ($n=1$), or a history of claustrophobia ($n=3$). Magnetic resonance images were obtained using a 3 T MAGNETOM Skyra scanner (Siemens Healthcare, Erlangen, Germany).

For patients with a history of previous TURBT surgery, imaging was scheduled at least 2 weeks after surgery to mitigate the potential impact of inflammatory changes on imaging results. Participants were hydrated approximately 30 min before the imaging session.

The study involved the examination of bladder tumor size, VI-RADS scores, clinical diagnoses, histopathological results after mpMRI, histopathological outcomes after surgery, and final histopathological results following repeat TURBT (Re-TURBT) or radical cystectomy. Interpretation of the study was conducted by a radiologist with substantial experience in urology and four pathologists with expertise in bladder tumors. The radiologist involved in the study has been working as an associate professor for 8 years and as a professor for 2 years alongside academic research, following 12 years of experience as a radiology specialist. They have been conducting numerous studies on genitourinary system radiology for 5 years. All identified lesions were scored according to the VI-RADS criteria published in the *European Journal of Urology* [6]. In instances where multiple lesions were present, the lesion with the higher score was prioritized for evaluation.

A total of 72 patients underwent mpMRI. However, six patients were excluded from a follow-up due to the absence of malignant pathology in their bladders; one lacked sufficient bladder fullness; another exhibited mpMRI results of insufficient image quality for diagnostic evaluation; and one patient, despite scoring, did not undergo any surgical procedure. Consequently, data from 63 patients were included in the study (Fig. 1).

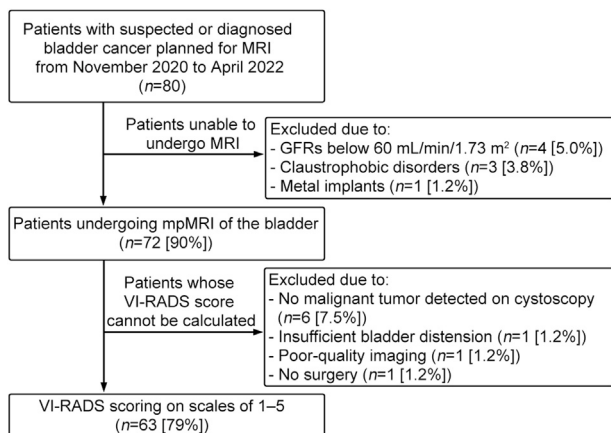


Figure 1 The study design. mpMRI, multiparametric MRI; VI-RADS, Vesical Imaging Reporting and Data System; GFR, glomerular filtration rate.

The data in this study were presented as the mean with standard deviation (SD), median (range), and number (percentage) based on variable types. Qualitative variables were compared between groups using the Pearson Chi-square test, and the significance test of the difference between two percentages (rates) was employed to compare the ratios (percentages) of the groups. The logistic regression analysis was performed to explore the relationship between muscle invasion and VI-RADS and tumor volume variables. A statistical significance level of $p < 0.05$ was accepted for the analyses. The data analysis was performed by using IBM SPSS Statistics (version 25.0 for Windows, IBM Corporation, Armonk, NY, USA).

3. Results

In our study, a total of 63 patients, including 60 males and three females, were enrolled. The mean age of the study participants was calculated as 64.2 (SD 10.5) years. Additionally, 39 (61.9%) patients were smokers, while 24 (38.1%) patients were non-smokers. Occupational exposure was found in only one (1.6%) patient.

Upon patient admission, 41 (65.1%) patients were diagnosed with primary bladder tumors, one (1.6%) patient with recurrent bladder tumor, and six (9.5%) patients with pathological high-grade T1 (T1HG) bladder tumors requiring repeat resection. Three (4.8%) patients were diagnosed with pathological T2 bladder tumors, and cystectomy was planned for this patient group, while 12 (19.0%) patients were included in the group undergoing subtotal resection.

For cases with multiple focal tumors, the one with the highest VI-RADS score was considered. Tumor volumes ranged from 0.2 cm³ to 239.0 cm³, with a mean tumor volume of 23.6 cm³.

As shown in Table 1, there were four patients with a VI-RADS score of 1, all of whom were included in the patient group with primary bladder tumors, and muscle invasion was not detected histopathologically in these four patients. Two patients with a VI-RADS score of 2 were also included in the patient group with primary bladder tumors, and muscle invasion was not detected histopathologically in both patients.

Four patients had a VI-RADS score of 3, three of whom were in the patient group with primary bladder tumors, and one was in the group of patients who underwent subtotal resection. In all four patients, muscle invasion was not detected histopathologically. Twenty of 27 patients with a VI-RADS score of 4 were included in the patient group with primary bladder tumors. Three of these patients were in the subtotal resection patient group; two were in the pathological T1HG bladder tumor patient group; and two were in the pathological T2 bladder tumor patient group. Muscle invasion was not detected histopathologically in fifteen of these patients, but it was detected in 12. There were 26 patients with a VI-RADS score of 5, of which 12 were in the patient group with primary bladder tumors, eight in the subtotal resection group, one in the recurrent bladder tumor group, four in the T1HG bladder tumor patient group, and one in the pathological T2 patient group. Muscle invasion was not detected histopathologically in five of these patients, but was detected in the other 21.

When all patients included in the study were examined, all (100%) of the four patients who received a VI-RADS score of 1 were found to have bladder tumors without muscle invasion. All (100%) of the two patients who received a VI-RADS score of 2 were found to have bladder tumors without muscle invasion. All (100%) of four patients who received a VI-RADS score of 3 were also found to have bladder tumors without muscle invasion. Twelve (44.4%) of the 27 patients with a VI-RADS score of 4 were found to have bladder tumors with muscle invasion, while 15 (55.6%) had bladder tumors without muscle invasion. Of the 26 patients with a VI-RADS score of 5, 21 (80.8%) had bladder tumors with muscle invasion, while 5 (19.2%) had bladder tumors without muscle invasion (Fig. 2).

According to the VI-RADS score, a comparative analysis between groups was conducted to demonstrate bladder wall muscle invasion. Significant differences were observed

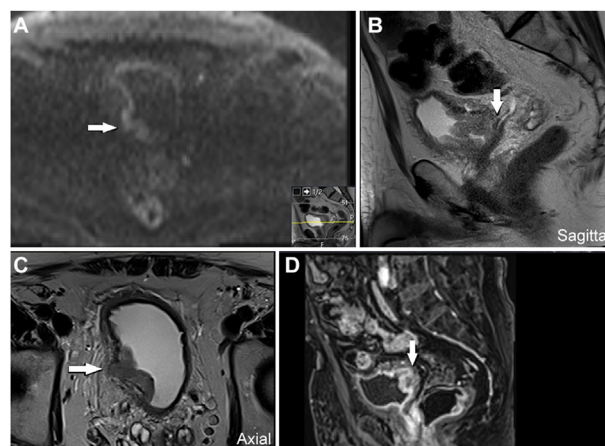


Figure 2 An example case of a 57-year-old man with pathological T3 urothelial carcinoma. (A) Right posterolateral wall (arrow) of the bladder showing diffusion restriction on diffusion-weighted series; (B and C) T2-weighted series showing that the lesion has reached the perivesical area (arrow) beyond the muscular layer; (D) Contrast-enhanced fat-suppressed sagittal T1 series showing a solid appearance with marked contrast enhancement.

Table 1 The number of patients and efficacy of the VI-RADS score in demonstrating muscle invasion.

VI-RADS score	Presence of muscle invasion		p-Value	Total
	Yes, n (%)	No, n (%)		
1	0 (0)	4 (13.3)	0.040*	4
2	0 (0)	2 (6.7)	0.2	2
3	0 (0)	4 (13.3)	0.040*	4
4	12 (36.4)	15 (50.0)	0.5	27
5	21 (63.6)	5 (16.7)	0.001*	26
Total	33 (52.4)	30 (47.6)	<0.001*	63 (100.0)

VI-RADS, Vesical Imaging Reporting and Data System.

* Statistically significant.

when scores were looked at as a whole ($p < 0.001$). A significant difference was found in the muscle invasion status of patients with a VI-RADS score of 1 ($p = 0.040$). Although none patients with a VI-RADS score of 2 had tumors with muscle invasion, there was no significant difference in the muscle invasion status detected due to an insufficient number of patients ($p = 0.2$). A significant difference was found in the muscle invasion status detected in patients with a VI-RADS score of 3 ($p = 0.040$). There was no significant difference in terms of detecting muscle invasion in the patient group with a VI-RADS score of 4 ($p = 0.5$), with 36.4% of the patients with muscle invasion in the study. A significant difference was found in the muscle invasion status detected in patients with a VI-RADS score of 5 ($p = 0.001$; Table 1).

The VI-RADS scores—obtained via mpMRI—of all study participants were compared against their histopathological

Table 2 Efficacy of muscle invasion detection in patients with VI-RADS scores of >3 and <3 .

Metrics	Value	95% CI	
		Lower	Upper
Accuracy	66	54	78
Sensitivity	100	89	100
Specificity	23	9	44
Positive predictive value	62	48	75
Negative predictive value	100	54	100

CI, confidence interval; VI-RADS, Vesical Imaging Reporting and Data System.

Note: Values are presented as percentage.

results. The performance of the VI-RADS score in differentiating between muscle-invasive bladder tumors and non-muscle-invasive bladder tumors was evaluated using the receiver operating characteristic curve analysis.

The accuracy rate of this study has been calculated as 66%, indicating that it is a reliable study. When patients with VI-RADS scores of 1 and 2 (*i.e.*, patients with VI-RADS scores of <3) were considered as having non-muscle-invasive bladder tumors and patients with VI-RADS scores of 4 and 5 (*i.e.*, patients with VI-RADS scores of >3) were considered as having muscle-invasive bladder tumors, the sensitivity of the VI-RADS score was 100%; specificity was 23%; the negative predictive value was 100%; and the positive predictive value was 62% (Table 2).

The VI-RADS score and tumor volume were evaluated, and it was found that the VI-RADS score alone was significant ($p = 0.030$). However, there was no significant correlation between tumor volume and the predictive accuracy of the VI-RADS scores for detecting the presence of muscle invasion ($p = 0.5$; Table 3).

4. Discussion

TURBT remains the gold standard for the initial diagnosis and treatment of non-muscle-invasive bladder cancer. Obtaining detrusor muscle in TURBT specimen has been demonstrated as a surrogate marker of resection quality. Moreover, a deep resection is considered essential to reduce the risk of residual disease, and the absence of detrusor muscle at pathologic report was widely demonstrated to be independently associated with an increased risk of early recurrence. Therefore, obtaining detrusor muscle in TURBT specimen is recommended by European Association of Urology guidelines for every resection [9]. The staging cannot be performed in the TURBT surgery performed in bladder tumor patients because the biopsy does not always include a bladder muscle sample, or because muscle samples collected are not taken from deep-seated regions of the tumor. In this regard, when Naselli et al. [10] examined repeated biopsies of patients whose initial histopathological diagnosis indicated a non-muscle-invasive bladder tumor, it was found that approximately 10% of these patients had muscle-invasive bladder tumors.

Staging bladder tumors and deciding on the most optimal approach to the early diagnosis and treatment of this disease are critical. In particular, MRI with morphological (T2W) and functional (DCE and DWI) sequences has been

Table 3 The relationship between the VI-RADS score and tumor volume.

VI-RADS score and tumor volume	Coefficient	SE	Wald	p-Value	OR	95% CI	
						Lower	Upper
VI-RADS score	1.480	0.683	4.700	0.030*	4.391	1.152	16.731
Tumor volume, cm ³	-0.038	0.072	0.275	0.6	0.963	0.837	1.109
Tumor volume via VI-RADS, cm ³	0.011	0.017	0.396	0.5	1.011	0.978	1.044
Constant	-6.575	2.88	5.211	0.022*	0.001	NA	NA

CI, confidence interval; NA, not applicable; OR, odds ratio; SE, standard error; VI-RADS, Vesical Imaging Reporting and Data System.

* Statistically significant.

shown to have high sensitivity and specificity in studies on this subject. In 2018, Panebianco et al. [6] aimed to provide standardization in the local staging of bladder tumors using VI-RADS criteria.

In a retrospective study conducted by Kim [11] in 2020, they investigated the diagnostic performance of the VI-RADS score. In their study, when tumors with VI-RADS scores of >3 were considered muscle-invasive bladder tumors, the sensitivity of the VI-RADS score was 91%, and the specificity was 76%. When tumors with VI-RADS scores of ≥ 3 were considered muscle-invasive bladder tumors, the sensitivity was 95%, and the specificity was 44% [11]. Therefore, in our study, it was recommended that we consider tumors with a VI-RADS score of 3 to be non-muscle-invasive bladder tumors. In our study, when a VI-RADS score of 3 was accepted as indicating a non-muscle-invasive bladder tumor, the calculated sensitivity of the VI-RADS score was 100% and the specificity was 33%. When the VI-RADS score of 3 was accepted as indicating a muscle-invasive bladder tumor, the calculated sensitivity was 100% and the specificity was 20%. In our study, a VI-RADS score of 3 was also indicative of a non-muscle-invasive bladder tumor. However, when all studies on this subject are evaluated, there is no common consensus that the VI-RADS score of 3 is indicative of a non-muscle-invasive bladder tumor. More studies are needed to reach such a consensus.

In a retrospective study in 2019, Wang et al. [12] investigated the performance of the VI-RADS system, which was used in examining 340 patients to detect muscle invasion in bladder tumors. In their study, when tumors with a VI-RADS score of ≥ 3 were considered as invading the bladder muscle, the sensitivity of the VI-RADS score was 87% and the specificity was 97%. However, the sensitivity value calculated for the T2W sequence was 89%, and the specificity was 71%. The sensitivity and specificity values for the DWI sequence were calculated as 87% and 97%, respectively. For the DCE sequence, the sensitivity and specificity values were found to be 89% and 95%, respectively. The muscle invasion was observed in all 56 patients with a VI-RADS score of 4 or 5, and muscle invasion was not observed in all 29 patients with a VI-RADS score of 1. The accuracy of detecting muscle invasion in tumors with VI-RADS scores of 1, 4, and 5 was reported as 100%. Thirty-three percent of the patients with a VI-RADS score of 3 did not have muscle invasion, while 67% had muscle invasion [12]. In our study, muscle invasion was not detected in any patients with a VI-RADS score of 3. This can be attributed to an insufficient number of patients with this score, and the patients not being evaluated by a single observer. In addition, in our study, all sequences (T2W, DWI, and DCE) were evaluated together, and statistical data analyses were performed on the VI-RADS scores to evaluate the predictive value of the scoring system in staging.

In a retrospective study published in 2020, Liu et al. [13] investigated the efficacy of the VI-RADS score in predicting. When tumors with a VI-RADS score of ≥ 3 were considered muscle-invasive tumors, the sensitivity of the VI-RADS system was 100%, and the specificity was 50%. All lesions assigned a VI-RADS score of 1 or 2 were non-muscle invasive. However, 32 out of the 35 lesions assigned a VI-RADS score of 3 were non-muscle invasive. For the lesions assigned a VI-RADS score of 4 or 5, the percentages of

muscle-invasive tumors were as high as 72.2% and 97.1%, respectively. Therefore, when a VI-RADS score of >3 is set as the cut-off value for a muscle-invasive status, both the sensitivity and specificity of the VI-RADS system can reach optimal levels [13]. When a VI-RADS score of 3 was defined as indicative of a non-muscle-invasive bladder tumor, results with high sensitivity were obtained, which is similar to the findings in our study.

The future clinical applications of the mpMRI and VI-RADS score in the management of bladder cancer have not yet been confirmed as a diagnostic tool for Re-TURBT candidates. Furthermore, an approach to avoid unnecessary secondary resection is still far from being achieved. However, mpMRI of the bladder might be considered for future predictive models to assess the risk of overstaged muscle-invasive bladder cancer after the initial resection, thus improving the adequate diagnosis and prognosis of bladder tumors.

It is important to determine the muscle invasion to determine the treatment strategy for bladder cancer. All studies performed on this subject to date have still not circumvented the histopathological diagnosis of biopsies taken via TURBT. Furthermore, cases such as a residual tumor remaining after biopsy samples have been collected and insufficient muscle samples in the biopsy material to provide adequate evaluation may result in muscle invasion going unnoticed. However, with the VI-RADS score developed using mpMRI, when the bladder is evaluated before surgery, a prediction of the muscle invasion status may offer an effective treatment opportunity by providing supplemental information on both the surgical procedure to be performed and the biopsy samples to be examined. Numerous studies have been conducted on this subject in recent years, and research is still ongoing. The significance of a VI-RADS score of 3 in this scoring system is still a point of debate regarding whether it indicates complete muscle invasion. In our study and in many other studies [11–13], using a VI-RADS score of 3 proved more effective for detecting non-invasive tumors.

Our study is subject to several prominent limitations that warrant careful consideration. Notably, the inadequacy of the patient cohort and the single-center design pose significant challenges. The restricted number of patients with VI-RADS scores of 2 and 3 in our study constitutes a specific constraint, particularly impacting the evaluation of these scores. The correlation between radiological and pathological findings in our study exhibited imperfections.

In the histopathological examination of TURBT biopsy samples from two patients with a VI-RADS score of 4, the initial assessment indicated a T1HG status. However, upon reevaluation of biopsy samples after Re-TURBT, the final pathology revealed a more advanced T2 status for these two patients. Similarly, a patient with a VI-RADS score of 5 initially received a histopathological evaluation of T1HG, but the subsequent pathology report after radical cystectomy indicated stages T2 initially and T4 later.

Confirmation regarding whether biopsy samples taken from patients with multiple focal bladder tumors precisely matched the lesions detected in the VI-RADS examination remains uncertain. Furthermore, the absence of radical cystectomy for all patients prevented a fully definitive

histopathological evaluation, representing another notable limitation of the study.

When considering these limitations, expanding multicenter studies and reaching a higher number of patients can enhance the robustness of the results in this field by evaluating the data more comprehensively and carefully through blinded analysis studies.

5. Conclusion

This study provides valuable insights that can contribute to more informed treatment planning and guide the selection of appropriate treatment modalities for patients with bladder tumors. The data obtained shed light on both the quality and quantity of tumors in these patients, offering essential information for clinical decision-making.

The VI-RADS score demonstrated notable efficacy, with scores of 1 and 2 proving highly effective in detecting non-muscle-invasive bladder tumors. Additionally, our findings suggest that VI-RADS scores of 4 and 5 are indicative of muscle-invasive bladder tumors, although these scores exhibit a lower frequency compared with other VI-RADS scores. These results underscore the promising role of mpMRI in the preoperative staging of bladder cancer.

However, it is crucial to acknowledge that further validation, development, and standardization of these findings are necessary. Especially, having a significant number of patients in each scoring system will yield meaningful results, and selecting multiple pathologists and radiologists for randomized controlled studies, as well as having multicenter studies, will increase the accuracy of the studies. Multicenter studies involving larger participant cohorts are imperative to enhance the reliability and generalizability of the data, ultimately advancing the role of mpMRI in the comprehensive management of bladder cancer.

Author contributions

Study concept and design: Hasan Gungor, Ahmet Camtosun.

Data acquisition: Hasan Gungor, Leyla Karaca.

Data analysis: Hasan Gungor, Leyla Karaca, Ibrahim Topcu.

Drafting of manuscript: Hasan Gungor, Ahmet Camtosun, Ibrahim Topcu.

Critical revision of the manuscript: Hasan Gungor, Ahmet Camtosun, Ibrahim Topcu.

Conflicts of interest

The authors declare no conflict of interest.

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