Original Article

Performance and Clinical Implications of VI-RADS in detecting muscle invasion in bladder tumors: A prospective observational study

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ABSTRACT

Introduction: Bladder cancer staging is pivotal for guiding therapeutic decisions. In this study, the primary objective was to assess the diagnostic accuracy of multiparametric magnetic resonance imaging (mpMRI), The study aimed to classify bladder tumors as either nonmuscle-invasive bladder cancers or muscle-invasive bladder cancers (MIBC) using the Vesical Imaging Reporting and Data System (VI-RADS) scoring. A secondary objective of the study focused on the accuracy of biparametric magnetic resonance imaging (bpMRI) in comparison to mpMRI.

Methods: Thirty-three patients with bladder tumors were enrolled and underwent both mpMRI and bpMRI scoring assessments. VI-RADS scores were assigned and subsequently compared with histopathological findings posttransurethral resection of bladder tumor., Statistical measures included sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy for VI-RADS scores at cutoff thresholds of ≥4 and 5.

Results: MpMRI at a VI-RADS cutoff of ≥4 yielded an 83.33% sensitivity and 100% specificity, with a diagnostic accuracy of 90.91%. At a cutoff of 5, sensitivity was 100%, specificity was 77.27%, and diagnostic accuracy was 84.85%. bpMRI at a cutoff of ≥4 showed an 80% sensitivity and 100% specificity, with diagnostic accuracy matching mpMRI at 90.91%.

Conclusions: This prospective analysis demonstrates that VI-RADS scoring with mpMRI provides reliable diagnostic accuracy for bladder cancer staging. mpMRI exhibits high sensitivity and specificity at a cutoff of ≥ 4, making it a robust tool for MIBC detection. bpMRI is an effective alternative in select patients. The study validates the use of VI-RADS scoring in clinical practice for effective treatment planning.

INTRODUCTION

Bladder cancer ranks as the tenth most common cancer globally, with approximately 570,000 cases reported as of 2020.[1] The majority of these cases are nonmuscle invasive bladder cancers (NMIBC), encompassing Ta, T1, and Tis pathological stages.[2] Differentiating NMIBC from muscle-invasive bladder cancer (MIBC) is critical for management decisions, emphasizing the need for accurate assessment of detrusor muscle infiltration before treatment.[3]

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Histopathological examination (HPE) from transurethral resection of bladder tumor (TURBT) samples, complemented by contrast-enhanced computed tomography, remains the standard for staging. The management of NMIBC typically involves transurethral resection of the tumor along with intravesical chemotherapy and immunotherapy depending upon the risk category, while MIBC and very high-risk NMIBC treatment protocols recommend neoadjuvant chemotherapy followed by radical cystectomy and adjuvant chemotherapy.[3]

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The Vesical Imaging Reporting and Data System (VI-RADS), established in 2018, offers a methodology for the preoperative determination of detrusor muscle invasion by tumor tissue.[4] This system, within the scope of multiparametric magnetic resonance imaging (mpMRI), has introduced criteria for T2-weighted (T2W), diffusion-weighted, and dynamic contrast-enhanced (DCE) imaging, establishing a 5-point VI-RADS scoring to guide treatment decisions.

Despite numerous studies, a reliable method for clinical staging remains elusive.[5-9] Therefore, the accuracy of VI-RADS scoring is crucial, especially when correlated with histopathological findings, to optimize treatment strategies. Previously published data underscored the efficacy of mpMRI with VI-RADS scoring in identifying MIBC and NMIBC. The available data on the utility of biparametric magnetic resonance imaging (bpMRI) for bladder tumors, particularly in the Indian population, is sparse.

The primary aim of this study was to compare the accuracy of VI-RADS scoring with the histological stage for preoperative staging of bladder cancer. The secondary objectives included comparing the diagnostic accuracy of biparametric scoring with the conventional mpMRI.

MATERIALS AND METHODS

Study setting and design

This observational study was conducted at a University Teaching Hospital, involving the Department of Urology and Renal Transplant, as well as the Department of Radiodiagnosis and Imaging. The study was conducted from May 2022 to April 2023.

Participants

The study sample comprised patients presenting with bladder tumors at the Department of Urology. A total of 33 patients who were admitted to our center during the 9-month period were enrolled into the study after obtaining their consent.

Eligibility criteria

Inclusion criteria

Patients of any age and gender presenting with primary bladder tumors, diagnosed through contrast-enhanced computed tomography (CT)/magnetic resonance imaging (MRI) scan or cystoscopy, were included.

Exclusion criteria

Patients with a history of bladder tumor surgery, prior history of chemotherapy, or radiotherapy for bladder tumor, contraindications to MRI, and histological presentations of nontransitional cell carcinoma or variant histologies were excluded from the analysis.

Imaging protocols

Patients underwent mpMRI, which incorporated T2W imaging, diffusion-weighted imaging (DWI), and DCE sequences. The imaging protocol adhered to a specific sequence, beginning with T2W imaging, followed by DWI, and concluding with DCE imaging. It is noteworthy that the administration of contrast is delayed until after acquiring the initial two sequences (T2W and DWI). This sequential approach ensures a systematic and comprehensive assessment of relevant anatomical and functional aspects before intravenous administration of contrast for enhanced visualization.

Image analysis

Two experienced radiologists specialized in urogenital imaging, independently reviewed and interpreted the MRI scans. The VI-RADS was employed to score images from both mpMRI and bpMRI. Disagreements between the radiologists were resolved by consensus. The VI-RADS scores ranged from 1 to 5, correlating with the increasing likelihood of muscle invasion.

Scoring criteria

The criteria for VI-RADS scoring, based on a 5-point Likert scale, were defined as follows:

- Score 1: Muscle invasion is highly unlikely
- Score 2: Muscle invasion unlikely
- Score 3: Equivocal for muscle invasion
- Score 4: Muscle invasion likely
- Score 5: Muscle invasion extending beyond the bladder is very likely.

Cutoff values for assessment

Two cutoff values, ≥4 and 5, were used to assess the diagnostic performance of both mpMRI and bpMRI. These values were critical in stratifying patients into NMIBC and MIBC categories.

Biological specimens and study procedures

Bladder tissue specimens collected after TURBT were analyzed. All patients underwent a second TURBT for accurate confirmation of the pathological stage obtained from the first TURBT specimen.

Data collection and analysis

Demographics and comprehensive clinical data were meticulously documented. Details from multiparametric mpMRI, including DWI, T2W imaging, DCE sequences, VI-RADS scoring, and HPE findings, were recorded in a case record form and analysed.

Statistical analysis

Data were collated using MS Excel 2019 and analyzed with the aid of Microsoft Excel and Epi Info software version 7.2.5. (Epi Info™ is a trademark of the Centers for Disease Control and Prevention (CDC). The Centers

for Disease Control and Prevention is the national public health agency of the United States. It is a United States federal agency under the Department of Health and Human Services, and is headquartered in Atlanta, Georgia.) Frequencies, percentages, means, and standard deviations constituted the primary statistical measures. Sensitivity, specificity, and diagnostic accuracy of VI-RADS scoring at cut-off points ≥4 and 5 were evaluated against HPE findings. Receiver operating characteristic curve analysis was employed to assess the diagnostic performance.

Ethical considerations

The Institutional Ethical Committee approved the study with the IEC approval number-IEC2: 66/2021, and informed consent was obtained from every patient involved in the research.

RESULTS

The study consisted of 33 patients diagnosed with primary bladder tumors. Our study included a diverse range of bladder tumors, encompassing papillary, solid, and broad-based tumors. The mean age of patients showed no significant difference between those with and without muscle invasion. Histopathological evaluation revealed that 54.55% (18 patients) of the tumors were muscle-invasive.

The distribution of T2W MRI scores across the cohort was as follows: 1 patient (3.03%) scored 1, 6 patients (18.8%) scored 2, 8 patients (24.24%) scored 3, 10 patients (30.3%) scored 4, and 8 patients (24.24%) scored 5. DWI results mirrored this distribution, as did the DCE MRI scores. Regarding VI-RADS scoring, the majority (18 patients) scored either 4 or 5.

At a VI-RADS cutoff value of ≥4, the sensitivity for detecting MIBC with mpMRI was 83.33% (95% confidence interval [CI]: 58.58%–96.42%), and the specificity was 100% (95% CI: 78.20%–100.00%) [Table 1]. At a cutoff value of 5, sensitivity reached 100% (95% CI: 71.51%–100.00%) and specificity was 77.27% (95% CI: 54.63%–92.18%) [Table 1]. The positive predictive value (PPV) at this higher threshold was 68.75% (95% CI: 50.45%–82.62%), with a negative predictive value (NPV) of 100% (95% CI: 80.49%–100.00%). The overall diagnostic accuracy was 90.91% (95% CI: 75.67%–98.08%) at a cutoff of ≥4 and decreased slightly to 84.85% (95% CI: 68.10%–94.89%) at a cutoff of 5 [Figures 1 and 2].

For bpMRI, the sensitivity at a cutoff of ≥4 was slightly lower at 80.00% (95% CI: 51.91%–95.67%), with a specificity of 100% (95% CI: 81.47%–100.00%) [Table 2]. At a cutoff value of 5, the sensitivity further decreased to 72.73% (95% CI: 39.03%–93.98%) and the specificity was 86.36% (95% CI: 65.09%–97.09%) [Table 2]. The PPV and NPV were 72.73% (95% CI: 46.72%–89.02%) and 86.36% (95% CI: 70.40%–94.40%), respectively, with an overall diagnostic accuracy of 81.82% (95% CI: 64.54%–93.02%) at this threshold.

DISCUSSION

The differentiation between MIBC and NMIBC is required for treatment planning. Some of the studies published during the past two decades found no significant differences in the diagnostic accuracy of multidetector computed tomography (MDCT) and MRI in bladder cancer staging.[10-13] In these studies, accuracy in detecting muscle invasion in bladder tumors ranged from 47% to 73% for MDCT and from 58% to 80% for MRI. mpMRI has managed to change the paradigm on bladder cancer detection and risk classification. It could also provide additional prognostic information and guide effective treatment decision-making.

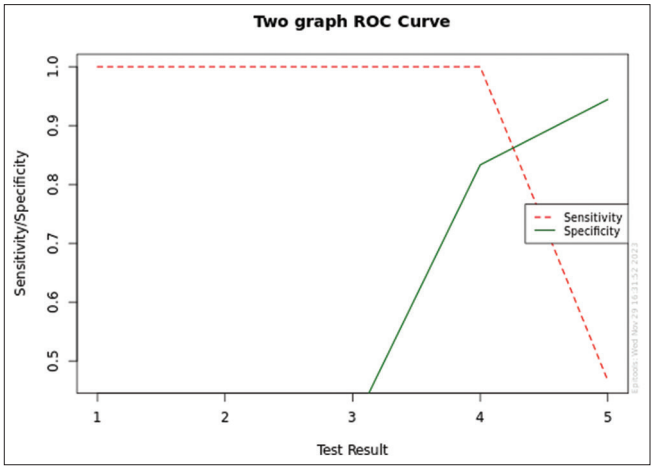

Figure 1: Sensitivity and specificity graph. ROC: Receiver operating characteristic curve

Table 1: Diagnostic accuracy of mp MRI - vesical imaging reporting and data system score

Statistic	Cut-off value of ≥4		Cut-off value of 5	
	Value (%)	95% CI	Value (%)	95% CI
Sensitivity	83.33	58.58%–96.42%	100.00	71.51%–100.00%
Specificity	100.00	78.20%–100.00%	77.27	54.63%–92.18%
Disease prevalence	54.55	36.35%–71.89%	33.33	17.96%–51.83%
PPV	100.00	78.20%–100.00%	68.75	50.45%–82.62%
NPV	83.33	64.02%–93.35%	100.00	80.49%–100.00%
Accuracy	90.91	75.67%–98.08%	84.85	68.10%–94.89%

PPV=Positive predictive value, NPV=Negative predictive value, CI=Confidence interval

Table 2: Diagnostic accuracy of biparametric magnetic resonance imaging at a cutoff value of ≥4 and 5

Statistics	Cutoff value of ≥4		Cutoff value of 5	
	Value (%)	95% CI	Value (%)	95% CI
Sensitivity	80.00	51.91%–95.67%	72.73	39.03%–93.98%
Specificity	100.00	81.47%–100.00%	86.36	65.09%–97.09%
Disease prevalence	45.45	28.11%–63.65%	33.33	17.96%–51.83%
PPV	100.00	73.54%–100.00%	72.73	46.72%–89.02%
NPV	85.71	68.56%–94.29%	86.36	70.40%–94.40%
Accuracy	90.91	75.67%–98.08%	81.82	64.54%–93.02%

PPV=Positive predictive value, NPV=Negative predictive value, CI=Confidence interval

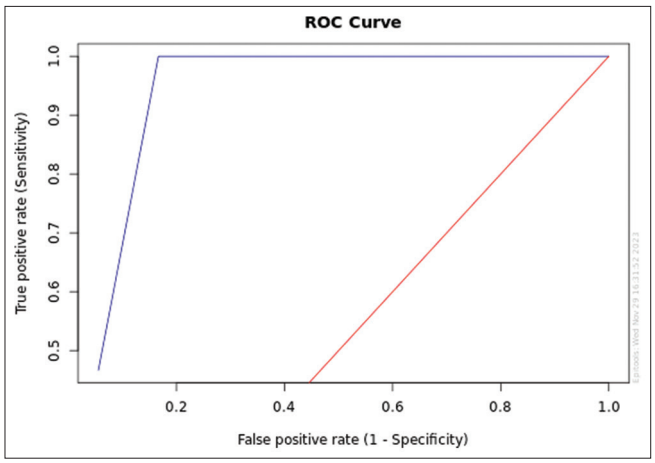

Figure 2: Graph of receiver operating characteristics curve. ROC: Receiver operating characteristics

The incorporation of T2W imaging enabled detrusor assessment, while DWI facilitated the evaluation of muscularis propria. In addition, DCE sequences offered precise information about the inner layer (bladder mucosa).[14] Although DCE provided detailed insights into the inner layer, the combined use of T2W and DWI imaging can also effectively assess the detrusor. This forms the foundation for a biparametric MRI approach in evaluating MIBC, particularly beneficial for patients with compromised glomerular filtration rate or those with contrast allergy.

Accurate clinical staging improves bladder cancer management, surgical planning, and patient outcomes.[15,16] mpMRI was reported and proved to be highly reliable in assessing MIBC.[17] In this study, the sensitivity and NPV of VI-RADS score at a cutoff of ≥4 for detecting MIBC were more compared to a cutoff value of 5 in detecting MIBC.

The results of our study indicate that mpMRI and bpMRI are valuable tools in the diagnosis of MIBC, with high diagnostic accuracy at different cutoff values. We aimed to assess the predictive accuracy of VI-RADS scores ≥4 and 5 individually, discerning their respective capacities for detecting muscle invasion. The mpMRI demonstrated excellent specificity at a VI-RADS cutoff of ≥4 and maintained high sensitivity at a cutoff of 5. The bpMRI showed a slight decrease in sensitivity and specificity at higher cutoff values. These findings are contextualized within the current diagnostic framework and suggest potential areas for clinical implementation, particularly avoiding gantry time and overall cost.

The sensitivity and specificity of mpMRI at a cutoff of ≥4 in our study were comparable to previously published data on the topic emphasizing the reproducibility of VI-RADS scoring across different demographics and settings.[17,18] The high specificity observed suggests that mpMRI, at this threshold, effectively rules out NMIBCs, which could significantly impact clinical decisions, steering patients away from unnecessary invasive procedures. This is particularly relevant given the high rates of residual tumors post-TURBT where accurate preoperative staging could potentially reduce the need for repeat surgeries.[19]

At a cutoff value of 5, our study demonstrated perfect sensitivity, mirroring findings from previous research.[20] Nonetheless, we observed a decrease in specificity, a phenomenon also noted in other studies.[21] This observed decline in specificity with an increased cutoff value from ≥4 to 5 in mpMRI, contrary to the expected increase, warrants a nuanced interpretation and highlights an important aspect of the VI-RADS reporting system. Typically, as the threshold for a positive test is raised, specificity should increase due to stricter criteria for a positive result, which would usually reduce false positives. However, several factors may contribute to the observed phenomenon (decline in specificity on raising the cutoff level) in our study. The VI-RADS scoring system, designed to evaluate the likelihood of muscle invasion, might capture features at higher scores that are indicative of aggressive NMIBC characteristics, leading to false positives. Subjectivity in interpreting imaging results can also contribute, as radiologists' perceptions of signs of invasion may vary, especially when distinguishing between advanced NMIBC and early MIBC. Image quality and interpretation variability, coupled with the inherent subjectivity of the VI-RADS system, can lead to overestimation of tumor invasiveness at higher scores. Furthermore, the selection of the cutoff value is critical, and if many MIBC cases cluster just above the lower threshold, increasing the cutoff might not significantly exclude true negatives, thus failing to enhance specificity. Understanding these dynamics is essential for refining the use of VI-RADS scoring in clinical practice and underscores the need for further research into the optimal application of this diagnostic tool. To bring it into clinical context, this

cutoff value may be more suitable in a high-risk population where the detection of MIBC takes precedence.

In our study, bpMRI showed a modest reduction in sensitivity at a cutoff of ≥4 and 5, a consequence typically anticipated due to the lack of contrast enhancement. Nevertheless, bpMRI maintained acceptable diagnostic accuracy, affirming its value as an alternative, particularly for patients in whom the first-generation gadolinium contrast media is contraindicated. Biparametric MRI can also contribute to cost reduction in resource-poor settings without losing its sensitivity and predictive value. While bpMRI's sensitivity and specificity at a cutoff of 5 fell short of mpMRI's, it still stands as a significant tool for bladder cancer staging, applicable to a broader patient demographic. The study's findings suggest that bpMRI's comparative accuracy merits its increased use in clinical settings, especially where resources are constrained, or contrast use is not an option.

Inter-observer agreement studies on comparing VI-RADS accuracy in the future and studies on cancers that arise from the bladder neck, trigone, and ureteral orifice are recommended.[22] Prior studies[23] evaluated interobserver agreement and diagnostic accuracy of VI-RADS. The interobserver agreement was estimated using intraclass correlation coefficients. Interobserver agreement was found to be excellent among five readers and diagnostic accuracy of VI-RADS was found to show area under the curve of 0.90. This value was similar to our study. All these studies indicate that VI-RADS is an ideal tool for treatment planning among bladder cancer patients. One study reported a sensitivity and specificity of MR imaging for TWI and DWI as 0.90 and 0.88, respectively, in differentiating MIBC and NMIBC.[24] Some studies reported that DWI images had higher accuracy for T staging of bladder cancer when compared to plain MR imaging modalities or CT imaging modalities.[25-27]

Residual tumors after TURBT were considered to be responsible for recurrence[28] and EAU guidelines suggest repeat TURBT (re-TURBT) for patients with high-risk bladder tumors.[29] During a re-TURBT, it is recommended that the surgeon includes resecting the base of the primary tumor. This additional step is undertaken to eradicate any potential residual disease that might be present and to ensure a more accurate pathological staging. Evidence suggests that there is a 51% risk of persistence of tumor and an 8% risk of under-staging when detrusor muscle is seen in the initial TURBT specimen.[30] Re-TURBT may impose additional health-care expenses on patients, and a second resection at the base of the primary tumor may increase the risk of bladder perforation, mainly for women.[31] Detection of muscle invasion reliably on noninvasive imaging such as mpMRI using a VI-RADS scoring system can help reduce the need for re-TURBT.

Overall, the study demonstrated that both mpMRI and bpMRI are effective diagnostic tools for MIBC, with high diagnostic accuracy at VI-RADS cutoff values of ≥4 and 5. The mpMRI showed excellent specificity at a cutoff of ≥4 and high sensitivity at a cutoff of 5. The bpMRI, while slightly less sensitive than mpMRI, was shown to be a valuable diagnostic option, particularly for patients in whom contrast media cannot be used. These findings align with previous studies, confirming the reliability of VI-RADS scoring in MIBC diagnosis. Despite a limited sample size and the absence of inter-reader variability assessment, the study contributes to the body of evidence supporting the use of MRI in bladder cancer staging and highlights the potential of bpMRI as an alternative imaging modality in certain patient populations.

The role of CT and positron emission tomography (PET)/CT in staging bladder cancer primarily focuses on evaluating nodal status and detecting distant metastasis. These imaging modalities offer limited accuracy in assessing local tumor stages, particularly in differentiating between T1 and T2 bladder tumors.[32] Unlike CT and PET/CT, mpMRI provides superior delineation of the bladder's local anatomy, making it highly effective in identifying muscle invasion. This precision is critical for accurately staging bladder cancer and tailoring appropriate treatment plans. Consequently, our study did not include a comparison with CT or PET/CT, as these modalities do not possess the necessary sensitivity and specificity for detecting muscle invasion. Instead, we focused on mpMRI and bpMRI due to their proven efficacy in local staging, which is essential for distinguishing between NMIBC and MIBC.

Despite its strengths, this study is not without limitations. The moderate sample size may limit the generalizability of the results. One reason for the small sample size is that our hospital serves a mixed socioeconomic population, with the majority being from lower socioeconomic strata. For these patients, the cost of mpMRI, when added to the overall management expenses, poses a significant financial burden. Second, we had to exclude patients who were already investigated with a contrast enhanced CT imaging performed at other centers and presented to our institution, as we could not repeat the investigations due to the financial constraints. Third, we excluded patients who underwent TURBT at other centers, regardless of whether it was a primary TURBT (partial or complete), or secondary TURBT. In addition, the study's design did not include a direct comparison with traditional diagnostic methods, which may impact the interpretation of the diagnostic accuracy of MRI modalities in the broader context of bladder cancer staging. The comparison between mpMRI and bpMRI was done in a nonrandomized fashion by the exclusion of the DCE sequence from the mpMRI cohort. Disagreements between the two radiologists confirm that consensus was employed as the means to address and resolve any disparities. Future research with larger cohorts and comparative designs will be essential to validate and expand on these findings.

While traditional histopathological confirmation remains the gold standard, the continuous advancements in imaging technologies and the integration of AI into clinical practice suggest a future where VI-RADS could significantly influence treatment decisions. This would streamline the management of bladder cancer, reduce the need for invasive procedures, and ultimately lead to better patient care outcomes.

CONCLUSION

Our study shows the diagnostic utility of VI-RADS scoring with multiparametric in the staging of bladder cancer. With a cutoff value of ≥4, mpMRI exhibited high specificity and substantial sensitivity for the detection of MIBC, offering a robust noninvasive diagnostic tool that could potentially reduce the need for more invasive procedures. bpMRI emerged as an alternative, particularly advantageous for patients in whom contrast-enhanced mpMRI is not viable. The consistency of our findings with previous research underscores the reliability of VI-RADS scoring across diverse patient populations and clinical settings. While the study's limited sample size and lack of inter-reader variability assessment point to areas for further research, the evidence presented supports the expanded use of MRI in the staging of bladder cancer, which is crucial for optimal treatment planning and patient management. Future studies should aim to include larger sample sizes and assess inter-reader agreement to solidify the generalizability of these results.

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