

VI-RADS SCORE IN DETECTING MUSCLE INVASION IN BLADDER TUMORS: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Bladder cancer is a common malignancy of the urinary tract, and preoperative differentiation between muscle-invasive bladder cancer (MIBC) and non-muscle-invasive bladder cancer (NMIBC) is increasingly emphasized, as multiparametric MRI can provide a more accurate, upfront impression of tumour invasiveness, helping clinicians anticipate the likely disease category even before formal pathological confirmation. The Vesical Imaging Reporting and Data System (VI-RADS), built on multiparametric MRI, offers a standardized and reproducible framework to evaluate the likelihood of detrusor muscle infiltration. In this context, the present study aimed to assess the diagnostic performance of VI-RADS in differentiating MIBC from NMIBC, using histopathological findings as the definitive reference standard. **Materials and Methods:** This prospective observational study was conducted in the Department of Urology and Renal Transplantation, Government Mohan Kumaramangalam Medical College and Hospital, Salem, Tamil Nadu, India, from May to October 2025. Fifty patients with suspected bladder tumours were enrolled, and 43 were included in the final analysis after applying exclusion criteria. All patients underwent mpMRI followed by transurethral resection of bladder tumour (TURBT), and VI-RADS scores were correlated with histopathology findings. **Result:** The study population included 33 males and 10 females, with a mean age of 68.5 years. Gross haematuria (100%) and chronic smoking (84%) were common. VI-RADS 2 was the most frequent score (34.9%). The system correctly identified 15 true MIBC and 20 true NMIBC cases, with 6 false positives and 2 false negatives. Diagnostic performance showed a sensitivity of 88.2%, specificity of 76.9%, positive predictive value of 71.4%, negative predictive value of 90.9%, and overall accuracy of 81.4%. **Conclusion:** VI-RADS demonstrated strong diagnostic accuracy for detecting muscle invasion in bladder cancer, supporting its role as a dependable preoperative imaging tool to guide appropriate treatment planning.

INTRODUCTION

Bladder cancer is a major malignancy of the urinary tract and contributes significantly to global cancer incidence.^[1] The global incidence of bladder cancer varies across regions, with higher rates observed in industrialised nations due to exposure to carcinogenic substances such as aromatic amines, cigarette smoking and chronic inflammation.^[2] Men are affected three to four times more than women, although women often present with more advanced disease at diagnosis. Because of its high recurrence and progression rates, bladder cancer is one of the

most expensive malignancies to manage on a per-patient basis throughout life, requiring repeated endoscopic procedures, intravesical therapies, and lifelong surveillance.^[3]

Most cases of bladder cancer are urothelial (transitional cell) carcinoma, classified into non-muscle-invasive (Ta, T1, Tis) and muscle-invasive ($\geq T2$) stages.^[4-6] Differentiating non-muscle-invasive bladder cancer (NMIBC) from muscle-invasive bladder cancer (MIBC) is crucial, as treatment approaches differ significantly. NMIBC is primarily managed with transurethral resection of bladder tumour (TURBT) with or without

intravesical chemotherapy, whereas MIBC often requires radical cystectomy with or without systemic chemotherapy.^[5,6] Accurate distinctions between these two stages not only determine the therapeutic approach but also influence prognosis and survival outcomes. Under staging may result in suboptimal treatment and tumour progression, while over staging may expose patients to unnecessary radical surgery. Therefore, reliable preoperative evaluation of muscle invasion remains a critical step in the management of bladder cancer.^[7,8]

Cystoscopy and transurethral resection are invasive and may not always provide adequate detrusor muscle tissue for histopathological confirmation, which can lead to underestimation of tumour stage. Imaging modalities like ultrasound and computed tomography (CT) also have limits in assessing the depth of bladder wall invasion due to poor soft-tissue resolution. In contrast, multiparametric magnetic resonance imaging (mpMRI) offers excellent soft-tissue contrast and allows detailed evaluation of bladder wall layers.^[9,10]

The Vesical Imaging Reporting and Data System (VI-RADS) was presented to standardise mpMRI reporting and improve diagnostic consistency for assessing muscle invasion.^[9] VI-RADS combines diffusion-weighted, T2-weighted, and dynamic contrast-enhanced MRI sequences into a five-point scoring system that ranges from definite non-muscle invasion (VI-RADS 1) to definite muscle invasion (VI-RADS 5). This structured system enhances reproducibility among radiologists and helps bridge radiological findings with clinical decision-making. Although several retrospective studies have shown encouraging results, only a few have prospectively validated VI-RADS.^[6,8,9]

This study aims to prospectively evaluate the diagnostic accuracy of mpMRI-based VI-RADS in distinguishing MIBC from NMIBC, using histopathological examination (HPE) as the reference standard.

MATERIALS AND METHODS

This prospective observational study was conducted at the Department of Urology and Renal Transplantation, Government Mohan Kumaramangalam Medical College and Hospital, Salem, Tamil Nadu, India, from May to October 2025. Ethical approval was secured from the institutional review board, and written informed consent was obtained from all participants before enrolment.

Inclusion and Exclusion Criteria

Patients admitted with a suspected bladder mass identified on ultrasonography, computed tomography, magnetic resonance imaging, or cystoscopy (performed elsewhere and referred without prior TURBT) were included.

Previous history of bladder surgery, chemotherapy, radiotherapy, contraindications to MRI, non-

transitional cell carcinoma, variant histology, carcinoma in situ on histopathology, incomplete evaluation after a T1 diagnosis, or refusal to participate were excluded.

Methods

Data on patient demographics, tumour grade, stage, and VI-RADS scores from preoperative mpMRI were collected and correlated with histopathological findings. After detailed history, blood tests, examination, and urine cytology, all eligible patients underwent 3 Tesla mpMRI of the bladder, including T2-weighted, diffusion-weighted, and dynamic contrast-enhanced sequences after ensuring adequate bladder distension with an antispasmodic and oral hydration. Two blinded urogenital radiologists independently assigned for calculating VI-RADS scores (1–5), with discrepancies resolved by consensus; a score ≥ 3 indicated muscle invasion. VI-RADS 1 indicates muscle invasion is highly unlikely, VI-RADS 2 indicates muscle invasion is unlikely, VI-RADS 3 represents an equivocal/uncertain probability of muscle invasion, VI-RADS 4 suggests muscle invasion is likely, and VI-RADS 5 indicates muscle invasion or extension beyond the bladder wall is very likely.

All patients underwent cystoscopy and TURBT under general anaesthesia using a 26 Fr bipolar resectoscope, with details of the number, site, size, and morphology of tumours, carcinoma in situ, and bladder mucosa recorded. Deep biopsies from the tumour base were obtained, and all specimens were sent separately for histopathological examination. Patients with non-muscle-invasive disease (T1) underwent repeat TURBT after two to six weeks. On final histopathology, NMIBC patients received adjuvant intravesical therapy and surveillance, while MIBC patients underwent radical cystectomy, radiotherapy, chemotherapy, or combined treatment as appropriate. Histopathology results were compared with preoperative VI-RADS scores for analysis. Of the 50 patients initially enrolled, four were excluded before MRI/TURBT due to contraindications, one was excluded after TURBT for squamous cell carcinoma, and two were lost to follow-up, leaving 43 patients for final analysis.

Statistical Analysis

Data were analysed using IBM SPSS Statistics v27 and were expressed as frequencies and percentages. Sensitivity, specificity, PPV, and NPV were calculated using VI-RADS scores of 3 and 4 as cut-off values.

RESULTS

All patients presented with gross haematuria, and most (84%) had a history of chronic smoking. After exclusions and losses to follow-up, 43 patients (33 males, 10 females) were included in the final analysis. [Table 1]

Table 1: Demographic and clinical characteristics

Characteristic	Category	N (%)
Sex distribution (initially n=50)	Male	37 (74%)
	Female	13 (26%)
Mean age (years)		68.5 (Range: 48–88)
History of gross haematuria		50 (100%)
History of chronic smoking		42 (84%)
Excluded before MRI/TURBT		4 (8%) (3 males, 1 female)
Underwent MRI and TURBT		46 (92%)
Excluded after TURBT	Squamous cell carcinoma on HPE (female)	1 (2%)
Lost to follow-up (2 males)		2 (4%)
Final patients analysed		43 (86%)
Sex distribution (final group n=43)	Male	33 (76.7%)
	Female	10 (23.3%)

VI-RADS 2 was the most common score, observed in 15 patients (34.9%), followed by VI-RADS 1,5,3,4 in 7 patients each (16.3%). Urine cytology was positive in 22 patients (51.16%). Cystoscopy revealed a single bladder lesion in 30 patients (69.7%) and multiple lesions in 13 patients (30.3%). Regarding surgical management, 35 patients (81.3%) underwent complete TURBT, 6 patients (14.0%)

underwent radical cystectomy, and 2 patients (4.7%) underwent partial cystectomy. Among the 17 patients with muscle-invasive bladder cancer, 8 underwent cystectomy (6 radical and 2 partial), while the remaining 9 were managed with TURBT alone at the time of analysis due to planned chemotherapy, medical unfit, or pending definitive treatment. [Table 2]

Table 2: Radiological, cytological, and surgical findings

Parameter	Category	N(%)
VI-RADS score (n=43)	1	7 (16.3%)
	2	15 (34.9%)
	3	7 (16.3%)
	4	7 (16.3%)
	5	7 (16.3%)
Urine cytology positive		22 (51.16%)
Cystoscopy findings before TURBT	Single bladder lesion	30 (69.7%)
	Multiple bladder lesions	13 (30.3%)
Type of surgical intervention	Radical cystectomy	6 (14%) (5 males, 1 female)
	Partial cystectomy	2 (4.7%) (both males)
	Complete TURBT	35 (81.3%)

VI-RADS 1–2 were mainly associated with small (≤ 3 cm) tumours in 18 patients (41.86%), most of which were low grade (16; 37.21%) and non-muscle-invasive (20; 46.51%). VI-RADS 3 included 7 patients (16.28%) with predominantly high-grade tumours (4; 9.30%) and low-grade tumours in 2 patients (4.65%), along with 4 non-muscle-invasive and 2 muscle-invasive cases. VI-RADS 4–5

comprised 14 patients (32.56%), predominantly harbouring large (>3 cm) tumours (12; 27.91%), all of which were high grade (14; 32.56%) and showed muscle-invasive pathology in most cases (13; 30.23%). Male patients constituted the majority across all VI-RADS categories (33; 76.74%). [Table 3]

Table 3: Distribution of tumour and patient characteristics according to VI-RADS scores

Patient characteristic	Category	VI-RADS 1	VI-RADS 2	VI-RADS 3	VI-RADS 4	VI-RADS 5
Sex	Male	5 (11.63%)	12 (27.91%)	5 (11.63%)	6 (13.95%)	5 (11.63%)
	Female	2 (4.65%)	3 (6.98%)	2 (4.65%)	1 (2.33%)	2 (4.65%)
Tumour Diameter	≤ 3 cm	7 (16.28%)	11 (25.58%)	2 (4.65%)	2 (4.65%)	1 (2.33%)
	> 3 cm	0 (0%)	4 (9.30%)	4 (9.30%)	6 (13.95%)	6 (13.95%)
Tumour Grade	High grade	1 (2.33%)	5 (11.63%)	4 (9.30%)	7 (16.28%)	7 (16.28%)
	Low grade	6 (13.95%)	10 (23.26%)	2 (4.65%)	1 (2.33%)	0 (0%)
Histopathology	NMIBC	7 (16.28%)	13 (30.23%)	4 (9.30%)	2 (4.65%)	0 (0%)
	MIBC	0 (0%)	2 (4.65%)	2 (4.65%)	6 (13.95%)	7 (16.28%)

The results showed that 15 patients with MIBC and 6 patients with NMIBC were correctly identified as having a positive VI-RADS score (>3), while 2 patients with MIBC and 20 patients with NMIBC were classified as negative (VI-RADS 1–2). The

diagnostic performance of VI-RADS showed a sensitivity of 88.2%, specificity of 76.9%, positive predictive value of 71.4%, negative predictive value of 90.9%, and an overall accuracy of 81.4%. [Table 4 and 5]

Table 4: Correlation of VI-RADS score with histopathological findings (n = 43)

Category	True MIBC (HPE)	True NMIBC (HPE)
VI-RADS >3 (Positive test)	15	6
VI-RADS 1-2 (Negative test)	2	20

Table 5: Diagnostic performance of VI-RADS in detecting muscle invasion

Parameter	Result
Sensitivity	88.2%
Specificity	76.9%
Positive predictive value (PPV)	71.4%
Negative predictive value (NPV)	90.9%
Accuracy	81.4%

DISCUSSION

This study assessed VI-RADS accuracy in differentiating muscle-invasive from non-muscle-invasive bladder cancer. Among 43 patients, VI-RADS showed high diagnostic accuracy, with gross haematuria, smoking history, and TURBT predominating. The study was conducted with predominantly male patients, with a mean age of 68.5 years. Most presented with gross hematuria and a history of chronic smoking, with 43 patients included in the final analysis. Similarly, Prakash et al., males constituted 84% and females 16% of the cohort, with a male-to-female ratio of 5.25:1.12.^[11] Hussain et al., the patients' ages ranged from 18 to 88 years. In a retrospective study on bladder carcinoma, 93.3% of patients presented with gross hematuria, and 73.3% had a history of smoking.^[12] Piramide et al., after exclusion of 5 post-TURBT and 2 inverted papilloma cases, 133 patients were analysed.^[13] These findings indicate that high-risk behaviours and age explain bladder cancer predominance in older males, emphasising the need for early screening and lifestyle modification strategies.

In our study, the VI-RADS scores among patients varied across all categories, with the majority of cases falling into the intermediate score range, indicating it was the most frequently observed category. Similarly, Wang et al. of 220 bladder cancer patients, VI-RADS 2 (27.73%) was most frequent, followed by VI-RADS 5 (28.18%) and VI-RADS 3–4 (16.36% each).^[14] da Silva et al. in a study of 200 bladder MRI examinations, VI-RADS 2 was most common (50.5%), followed by VI-RADS 5 (17.5%), VI-RADS 4 (12.5%), and VI-RADS 1 and 3 (6.5% each).^[15] This shows that intermediate VI-RADS scores emphasise the need for consistent imaging assessment.

Our study shows urine cytology was positive, with most patients having single lesions and fewer having multiple bladder lesions. Similarly, Abdullah found that in a study involving 191 patients with urothelial carcinoma, urine cytology yielded positive results in 70 patients, accounting for approximately 36.6% of the cases.^[16] Thus, urine cytology has a supportive role, but combining it with imaging and cystoscopy enhances diagnostic accuracy for bladder cancer.

In this study, surgical treatment primarily involved complete TURBT, with a few patients undergoing

radical or partial cystectomy, including both male and female patients. Similarly, Zheng et al. (66.6% underwent primary TURBT, while 28% underwent radical cystectomy as their initial surgical treatment.^[17] Anghel et al. of 155 patients with T2–T4 bladder carcinoma, 99 (63.9%) underwent repeated TURBT, while 56 (36.1%) received radical cystectomy as their surgical management.^[18] Therefore, complete TURBT as primary treatment reflects preference for bladder preservation; careful selection for radical surgery can improve treatment outcomes.

The present study shows that tumour characteristics differed by VI-RADS scores, with lower scores showing smaller, less invasive tumours, intermediate scores having mixed features, and higher scores associated with larger, high-grade, muscle-invasive tumours. Similarly, Del Giudice et al. found that lower VI-RADS scores (1–2) were associated with small tumours (≤ 3 cm; 83.3–86.9%), mostly T1, high grade in 80–86.6%, detrusor muscle present in 63.3–86.6%, and favourable Re-TURBT outcomes (absence of BCa 85–90%). Higher scores (4–5) showed large, high-grade tumours, full detrusor presence, and frequent upstaging to MIBC (87.5–100%).^[19] Reddy et al. of 33 bladder tumour patients, VI-RADS 1–5 were distributed as 3.03%, 18.8%, 24.24%, 30.3%, and 24.24%, with high scores (4–5) showing 54.55% muscle-invasive disease.^[20] Overall higher VI-RADS scores indicate aggressive tumours; integrating VI-RADS with clinical and pathological data can improve staging accuracy and treatment planning.

Our study shows that VI-RADS is a reliable and accurate imaging system for differentiating individual muscle-invasive from non-muscle-invasive bladder cancers. Similarly, Metwally et al. of 331 patients, a VI-RADS cut-off value >3 demonstrated a sensitivity of 84.1% and a specificity of 92.3% for identifying muscle-invasive bladder cancer.^[21] Kim found in 297 patients with 339 tumours, a VI-RADS cut-off of ≥ 4 showed a sensitivity of 91.3% and specificity of 76.0%, while a cut-off of ≥ 3 increased sensitivity to 94.6% but reduced specificity to 43.9%.^[22] Islam et al., a VI-RADS cut off of ≥ 3 showed a sensitivity of 97.6%, specificity of 73.7%, PPV of 88.9%, and NPV of 93.3% for detecting muscle invasion.^[23] Therefore, VI-RADS shows high reliability for detecting muscle

invasion, showing that VI-RADS reliably detects muscle invasion in different patient groups.

Limitations

This single-centre study with a small sample size may limit generalisability. Interobserver variation, short follow-up, and selection bias from excluding previously treated patients could have influenced VI-RADS assessment and overall outcome interpretation.

CONCLUSION

VI-RADS is a reliable and accurate imaging system for muscle-invasive from non-muscle-invasive bladder cancer using multiparametric MRI. The strong correlation between VI-RADS scores and histopathological findings highlights its diagnostic value in preoperative staging. Its high sensitivity and specificity indicate its usefulness in guiding treatment planning and reducing diagnostic uncertainty. Incorporating VI-RADS into clinical practice can enhance decision-making, optimise patient management, and potentially reduce unnecessary invasive procedures. Further large-scale multicentre studies are recommended to validate these findings and standardise their clinical application.

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