

# Diagnostic accuracy of multiparametric MRI with vesical imaging reporting and data system scoring for differentiating muscle-invasive and nonmuscle-invasive bladder cancer: A prospective study

Original  
Article

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## ABSTRACT

**Background:** Accurate bladder cancer (BC) staging is crucial for appropriate treatment strategies. Recent advances in imaging technologies emphasize the potential of multiparametric MRI (mpMRI). This study aimed to evaluate the diagnostic accuracy of mpMRI in distinguishing between muscle-invasive BC and nonmuscle-invasive BC compared to conventional cystoscopy and histopathological examination. Also, if we can use mpMRI as a follow-up modality for BC, which may allow extending the time between follow-up cystoscopies.

**Patients and Methods:** This prospective study included 30 BC patients. Eligible patients underwent history, physical examination, radiology, and laboratory tests. Excluded patients had various contraindications. Preoperative mpMRI was performed, and then diagnostic cystoscopy and transurethral resection of the bladder tumor, with histopathological examination, were done.

**Results:** The study involved 30 (93.3% male) patients with a mean age of 64.1 years. mpMRI vesical imaging reporting and data system (VI-RADS) scoring demonstrated high diagnostic performance in diagnosing muscle invasion in newly diagnosed cases with BC, with an area under the curve of 91.3%, sensitivity of 100%, and specificity of 82.6%. In diagnosing muscle invasion in cases presented for their routine follow-up of BC, mpMRI VI-RADS scoring had an area under the curve of 95%, sensitivity of 100%, and specificity of 90%.

**Conclusion:** This study highlights mpMRI with VI-RADS scoring as a valuable diagnostic tool for differentiating muscle-invasive BC from nonmuscle-invasive BC and also detecting the presence of bladder masses in known BC patients during their routine follow-up. The findings suggest that mpMRI could serve as a less invasive alternative to cystoscopy in case of bladder mass absence, improving patient care and reducing risks associated with invasive procedures.

**Key Words:** Bladder cancer, diagnostic accuracy, multiparametric MRI, muscle-invasive bladder cancer, vesical Imaging Reporting and Data System.

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## INTRODUCTION

Bladder cancer (BC) is a prevalent malignancy worldwide, presenting significant challenges for healthcare providers and patients alike<sup>[1]</sup>. Accurate staging of bladder cancer is crucial for tailoring appropriate treatment strategies, as muscle-invasive bladder cancer (MIBC) and nonmuscle-invasive bladder cancer (NMIBC) require distinct therapeutic approaches<sup>[2,3]</sup>. Consequently, precise differentiation between MIBC and NMIBC plays a critical role in improving patient outcomes and optimizing healthcare resources<sup>[4]</sup>.

Currently, the gold standard diagnostic technique for bladder cancer is transurethral resection of bladder tumor

(TURBT), followed by histopathological examination of the obtained tissue samples<sup>[5]</sup>. While TURBT is essential for diagnosis and staging, its success may be contingent upon the surgeon's skill level, and muscle layer sampling may be inadequate in a significant proportion of cases, leading to potential under-staging of invasive cancers<sup>[6]</sup>.

Recent advances in imaging technologies have highlighted the potential of multiparametric MRI (mpMRI) as an adjunctive tool for bladder cancer staging<sup>[7,8]</sup>. mpMRI combines anatomic T1 and T2-weighted imaging with functional sequences, such as diffusion-weighted imaging (DWI) and dynamic contrast-enhanced (DCE) MRI, to provide detailed information on tumor characteristics and local spread<sup>[9]</sup>. The vesical imaging reporting and

data system (VI-RADS score) has been introduced as a standardized method for assessing and reporting mpMRI findings in bladder cancer patients, facilitating consistent interpretation and communication of results<sup>[10]</sup>.

Several studies have investigated the performance of mpMRI in differentiating MIBC from NMIBC, reporting encouraging sensitivity and specificity rates, which could help overcome the limitations of TURBT<sup>[9,10]</sup>. Incorporating mpMRI into the diagnostic workup of bladder cancer patients may enhance the assessment of tumor invasion and extravesical extension, guiding clinicians in selecting the most appropriate treatment strategy for each patient<sup>[11]</sup>.

In this study, we aim to evaluate the diagnostic accuracy of mpMRI in distinguishing between MIBC and NMIBC, comparing its performance to the established methods of conventional cystoscopy and histopathological examination of biopsy specimens, as well as its accuracy in detecting the presence of bladder masses in patients known to have BC compared to follow-up cystoscopy.

## **PATIENTS AND METHODS:**

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### ***Study design and participants***

This prospective study was conducted throughout 11 months, from May 1, 2022 to April 1, 2023 on 30 patients either newly diagnosed with BC by diagnostic cystoscopy and histopathological examination of the resected specimen or patients are previously known to have BC and presented for their routine follow-up. Ethical approval was obtained from the ethical committee of the Faculty of Medicine at Helwan University (IRB no. REC-FMHU 51/202). Informed consent was obtained from the enrolled patients in the study, with clear, detailed information about risks, benefits, compensations, and the right to withdraw from the study at any time without penalty.

### ***Eligibility criteria***

All patients diagnosed with NMIBC, MIBC, or patients already known to have BC and presented for their routine follow-up cystoscopy were included without being restricted to age or sex. The study encompassed all histological types of bladder cancer, including newly diagnosed, recurrent cases, or even patients undergoing follow-up cystoscopy. On the other hand, patients with elevated renal function and patients with absolute contraindication to MRI (e.g. metallic prosthesis) were excluded.

### ***Sample size calculation***

The sample size calculation was performed using PASS 11. NCSS, LLC. Kaysville, Utah, USA, setting the power at 80% and the alpha error at 5%. Based on results from

a previous study<sup>[12]</sup>, the sample size of at least 30 patients was deemed sufficient to achieve the study objectives.

### ***Study procedures***

All patients were evaluated through history taking, physical examination, and laboratory tests, including complete blood count, serum creatinine, blood urea nitrogen, coagulation profile, aspartate transaminase, and alanine transaminase. mpMRI was performed preoperatively with a protocol that included a combination of T1 weighted image, high-resolution T2-weighted image (T2WI), DWI, and DCE.

The patients were instructed to drink water 1 h before mpMRI imaging to ensure examination with a full urinary bladder. Pelvic MRI was performed in the supine position using a 3T MRI scanner (Magnetom Skyra, Siemens Healthcare, Erlangen, Germany) with an 18-channel and phased array body coil. The entire pelvis was imaged, starting from the aortic bifurcation to the inferior margin of the symphysis pubis. The imaging protocol included conventional axial T1 weighted image, fast spin-echo T2WI, high-spatial-resolution T2WI, DW-MRI, and DCE-MRI.

The data of mpMRI are kept blind from the surgeons that are going to perform TURBT so as not to be biased with the result of MRI.

Then, diagnostic cystoscopy and TURBT were performed for the patients (if a bladder mass was found), and specimens were sent for histopathological examination as a gold standard for the diagnosis of BC and if there is muscle layer invasion, which was then compared with mpMRI done preoperatively.

Patients already known to have BC and presented for their routine follow-up cystoscopy were included. If no mass was found, this group was referred to as T0.

### ***Statistical analysis***

Statistical analysis was performed using IBM SPSS Statistics, version 28.0, NY, USA, for data analysis. Quantitative data were tested for normality with the Shapiro-Wilk test and described as mean±SD. Qualitative data were expressed as numbers and percentages and compared using Fisher's exact or  $\chi^2$  tests. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each diagnostic method. The receiver operating characteristic curve was used to calculate the area under the curve (AUC) and evaluate test performance in differentiating groups. A *P* value less than 0.050 was considered significant, otherwise nonsignificant.

## RESULTS:

### *Demographic characteristics and histopathological findings*

The study included 30 patients who completed the study, with a mean age of 64.1±9.3 years. Most participants were male (93.3%), and 26.7% were in their initial visit. Histopathological findings showed that 46.7% had a T0 grade, followed by T1 (30%), T2 (13.3%), and T3 (10%). Muscle invasion was found in 23.3% of cases.

### *Multiparametric MRI findings*

Less than half of the studied cases had VI-RADS I (46.7%), while VI-RADS II, IV, and V were 13.3, 3.3, and 36.7%, respectively. Muscle invasion was found in 40% of cases. For patients with follow-up visits, muscle invasion was observed in 23.1% of cases. A significant linear association was found between mpMRI findings (VI-RADS scoring) and histopathology staging (T stages) with a *P* value less than 0.001. VI-RADS V was statistically more frequent among cases with invasion than those without invasion (*P*<0.001), as shown in (Tables 1 and 2).

### *Diagnostic performance of multiparametric MRI vesical imaging reporting and data system*

mpMRI VI-RADS scoring showed a high AUC 91.3% [95% confidence interval (CI): 81.1–100%; *P*<0.001] in diagnosing baseline muscle invasion, with a sensitivity of 100% (95% CI: 59.0–100.0%), specificity of 82.6% (95% CI: 61.2–95.0%), accuracy of 86.7% (95% CI: 69.3–96.2%), PPV of 63.6% (95% CI: 30.8–89.1%), and NPV of 100% (95% CI: 82.4–100.0%).

For diagnosing the baseline presence of bladder cancer, mpMRI with VI-RADS scoring had perfect diagnostic performance, with the best cut point being VI-RADS II. The AUC was 100% (95% CI: 100–100%; *P*<0.001), with a sensitivity of 100% (95% CI: 79.4–100.0%), specificity of 100% (95% CI: 76.8–100%), accuracy of 100% (95% CI: 88.4–100%), PPV of 100% (95% CI: 79.4–100%), and NPV of 100% (95% CI: 76.8–100.0%).

In diagnosing muscle invasion in cases with follow-up, mpMRI VI-RADS scoring had high diagnostic

performance, with the best cut point being VI-RADS V. The AUC was 95% (95% CI: 86.7–100%; *P*=0.001), with a sensitivity of 100% (95% CI: 54.1–100.0%), specificity of 90% (95% CI: 68.3–98.8%), accuracy of 92.3% (95% CI: 74.9–99.1%), PPV of 75% (95% CI: 34.9–96.8%), and NPV of 100% (95% CI: 81.5–100.0%), as shown in (Table 3, Figs 1 and 2).

**Table 1:** Demographic characteristics and histopathological findings

Characteristics	Mean±SD	Range
Age (years)	64.1±9.3	47.0–83.0
		<i>n</i> (%)
Sex		
Male	28 (93.3)	
Female	2 (6.7)	
Visit		
Initial	8 (26.7)	
Follow-up	22 (73.3)	
Stage		
T0	14 (46.7)	
T1	9 (30.0)	
T2	4 (13.3)	
T3	3 (10.0)	
Invasion		
Muscle invasion	7 (23.3)	
No muscle invasion	23 (76.7)	

**Table 2:** Multiparametric MRI findings

MRI VI-RADS	Histopathology [ <i>n</i> (%)]	
	Muscle invasion (Total=7)	No muscle invasion (Total=23)
I	0	14 (60.9)
II	0	4 (17.4)
IV	0	1 (4.3)
V	7 (100.0)	4 (17.4)
<i>P</i> value	<0.001*	

VI-RADS, vesical imaging reporting and data system.

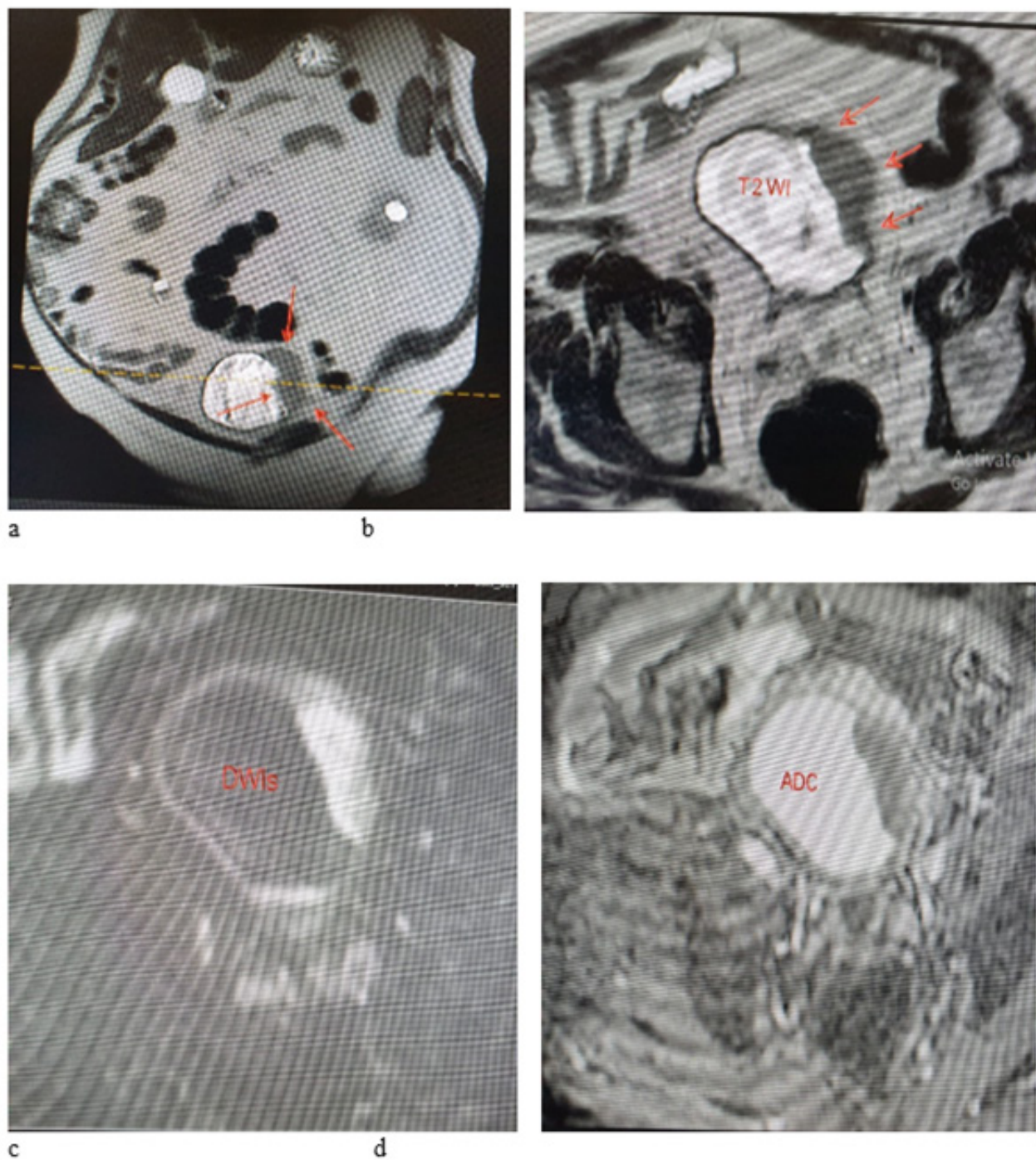
**Table 3:** Diagnostic performance of multiparametric MRI vesical imaging reporting and data system

Characteristics	Baseline muscle invasion		Baseline presence of bladder cancer		Muscle invasion in cases presented for follow-up	
	Value	95% CI	Value	95% CI	Value	95% CI
AUC	0.913	0.811–1.000	1.000	1.000–1.000	0.950	0.867–1.000
<i>P</i> value	0.001*		<0.001*		0.001*	
Cut point	VI-RADS V		≥VI-RADS II		VI-RADS V	
Sensitivity	100.0%	59.0–100.0%	100.0%	79.4–100.0%	100.0%	54.1–100.0%

**DIAGNOSTIC ACCURACY OF MULTIPARAMETRIC MRI**

Specificity	82.6%	61.2–95.0%	100.0%	76.8–100.0%	90.0%	68.3–98.8%
Diagnostic accuracy	86.7%	69.3–96.2%	100.0%	88.4–100.0%	92.3%	74.9–99.1%
Youden’s Index	82.6%	67.1–98.1%	100.0%	100.0–100.0%	90.0%	76.9–100.0%
Positive predictive value	63.6%	30.8–89.1%	100.0%	79.4–100.0%	75.0%	34.9–96.8%
Negative predictive value	100.0%	82.4–100.0%	100.0%	76.8–100.0%	100.0%	81.5–100.0%

AUC, area under the curve; VI-RADS, vesical imaging reporting and data system.



**Fig. 1:** mpMRI of a male patient 78 years old, showing a large mass at the left superior lateral wall involving the urinary bladder dome and measures 4.8x2.3x4.2 cm. (a and b) shows assessment with T2-weighted image with intermediate signal intensity that extends through the muscularis propria, invading the perivesical fat tissue with SC 5. (c and d) DWI (b=2000) and ADC maps show a lesion with significant restricted diffusion, extending through the muscularis propria, invading the perivesical fat tissue. DWI was assigned as SC 5. The overall VI-RADS score was 5. ADC, apparent diffusion coefficient; DWI, diffusion-weighted imaging; SC, structural category; VI-RADS, vesical imaging reporting and data system.



**Fig. 2:** mpMRI of a male patient 61 years old, with T1 urothelial carcinoma of the bladder (according to histopathology). A large mass is seen at the left superior lateral wall involving the urinary bladder dome and measures 4.4x1.1x3.8 cm. (a) Assessment with T2-weighted image with structural category (SC) 2. (b) On the DCE study, no early enhancement of the muscularis propria, with early enhancement of the inner layer of the tumor (CE2-category). (c) DWI showing nonrestricted inner part of the lesion with the core is noted, denoting polypoidal nature of the lesion with stalk noted, and the diffusion category is 2. The final VI-RADS score is 2. DCE, dynamic contrast-enhanced; DWI, diffusion-weighted imaging; VI-RADS, vesical imaging reporting and data system.

## DISCUSSION

The present study aimed to evaluate the sensitivity of mpMRI in differentiating between MIBC and NMIBC compared to the gold standard diagnostic methods of conventional cystoscopy and histopathological examination of biopsy samples. The demographic characteristics of our study population showed a predominance of male patients (93.3%), which aligns with the known higher incidence of bladder cancer in men compared to women<sup>[13]</sup>. Additionally, the distribution of histopathological grades in our study population was comparable to that reported in previous studies<sup>[14]</sup>. Our findings demonstrated the high diagnostic performance of mpMRI using the VI-RADS scoring system in accurately differentiating between MIBC and NMIBC, as well as detecting the presence of bladder cancer. This finding is in line with previous studies conducted by Juri *et al.*<sup>[15]</sup>, Wang *et al.*<sup>[16]</sup>, Woo *et al.*<sup>[17]</sup>, Makboul *et al.*<sup>[12]</sup>, and Del Giudice *et al.*<sup>[18]</sup>.

VI-RADS provides a valuable, standardized method for both acquiring and interpreting mpMRI data for bladder cancer. Furthermore, it allows for considerable interreader agreement, with high kappa values between 0.81 and 0.92<sup>[12,16,18–20]</sup>, and an intraclass correlation coefficient of 0.85<sup>[20]</sup>. Juri and colleagues conducted a study to assess whether the reduced field-of-view (rFOV) DWI sequence enhances the distinction between NMIBC and MIBC utilizing the VI-RADS. Their findings showed that the sensitivity, specificity, accuracy, and AUC for readers 1 and 2 using the rFOV DWI sequence were better than those with the full field-of-view DWI sequence. The average apparent diffusion coefficient values were comparable between the two sequences. They concluded that

the rFOV DWI sequence demonstrated superior diagnostic ability in differentiating between NMIBC and MIBC using VI-RADS, regardless of the readers' experience<sup>[15]</sup>. According to Barchetti and colleagues, when using a VI-RADS more than 2 cut-off to identify MIBC, reader 1 achieved 91% sensitivity and 89% specificity, while reader 2 attained 82% sensitivity and 85% specificity. The respective PPV and NPV were 77 and 96% for reader 1 and 69 and 92% for reader 2. With a VI-RADS more than 3 cut-off, sensitivity and specificity were 82 and 94% for reader 1, 77 and 89% for reader 2, and the corresponding PPV and NPV were 86 and 93% for reader 1, and 74 and 91% for reader 2. The AUC was 0.926 for reader 1 and 0.873 for reader 2, and interreader agreement was generally strong ( $K=0.731$ ), demonstrating the accuracy of VI-RADS in distinguishing MIBC from NMIBC<sup>[10]</sup>. Similarly, Makboul *et al.*<sup>[12]</sup> demonstrated that mpMRI had a sensitivity of 96%, specificity of 92%, PPV of 94%, and NPV of 95% for differentiating between MIBC and NMIBC.

Our study, using VI-RADS score 5 as a cut-off value, demonstrated a sensitivity of 100.0% and specificity of 82.6%. The higher sensitivity in our study may be attributed to the use of a 3 T MRI device, which has been shown to yield improved diagnostic performance compared to 1.5T MRI devices. Luo and colleagues, conducted a meta-analysis of six studies to assess the diagnostic performance of VI-RADS score for detecting MIBC. The pooled sensitivity, specificity, and AUC value for using VI-RADS 3 as the cut-off value were 90, 86, and 93%, respectively. In contrast, the corresponding estimates for VI-RADS 4 as the cut-off value were 077, 97, and 92%. They highlighted that the VI-RADS score offers a strong predictive ability for determining muscle invasiveness

in primary bladder cancer when using either VI-RADS 3 or VI-RADS 4 as the cut-off value<sup>[21]</sup>. Another recent meta-analysis of six studies showed that the pooled sensitivity and specificity of VI-RADS were found to be 0.83 (95% CI: 0.70–0.90) and 0.90 (95% CI: 0.83–0.95), respectively, with an area under the HS receiver operating characteristic curve of 0.94 (95% CI: 0.91–0.95). There was significant heterogeneity among the studies, which was influenced by factors such as the number of patients, magnetic field strength, T2-weighted image slice thickness, and VI-RADS cut-off score. The results indicate that VI-RADS demonstrates strong sensitivity and specificity in identifying MIBC. However, it is important to consider technical factors related to MRI acquisition and the choice of cut-off scores, as these can impact the performance of VI-RADS<sup>[17]</sup>. These findings highlighted that the VI-RADS scoring system effectively differentiates muscle-invasive from NMIBC with high sensitivity and specificity. It is important to consider technical factors and appropriate cut-off scores to optimize its performance.

The high diagnostic performance of mpMRI in our study, particularly in detecting the presence of bladder masses (T1–T4), highlights its potential as an effective tool for guiding appropriate treatment decisions. Accurate diagnosis and staging are critical for selecting the most suitable management approach, including transurethral resection, radical cystectomy, or chemoradiotherapy<sup>[4]</sup>. Moreover, the results of our study indicate that mpMRI can be particularly useful in the follow-up of patients with bladder cancer. The high diagnostic performance of mpMRI in detecting invasion during follow-up visits (AUC 95%) suggests that it can be an effective non-invasive alternative to repeated cystoscopies, which are invasive and may cause discomfort or complications for the patient<sup>[22]</sup>.

Several factors may have contributed to the robustness of our study's findings. We employed a prospective study design and used a 3 T MRI device, both of which have been recommended by previous studies to improve diagnostic performance. Moreover, we minimized potential sources of variability and error by ensuring that the same radiology, urology, and pathology teams were involved in the evaluation of all patients.

Despite its strengths, our study has certain limitations, including a relatively small sample size. The limited availability of 3T MRI machines in Egypt, high costs associated with the procedure, and exclusion of patients with specific contraindications (e.g. poor renal function, claustrophobia, inability to remain still during the scan) may have restricted the generalizability of our results.

## CONCLUSION

Our study highlights the potential of mpMRI with VI-RADS scoring as a valuable diagnostic tool in differentiating MIBC from NMIBC and detecting the presence of bladder masses in patients with known bladder cancer during routine follow-up. These findings suggest that mpMRI could serve as a less invasive alternative to cystoscopy and histopathological examination, improving patient care and reducing the risks associated with invasive procedures. Further research with larger sample sizes and diverse patient populations is warranted to validate and expand upon these findings.

## ABBREVIATIONS

AUC, area under the curve; CI, confidence interval; DCE, dynamic contrast-enhanced; DWI, diffusion-weighted imaging; MIBC, muscle-invasive bladder cancer; mpMRI, multiparametric MRI; NMIBC, nonmuscle-invasive bladder cancer; NPV, negative predictive value; PPV, positive predictive value; rFOV, reduced field-of-view; T2WI, high-resolution T2-weighted image; TURBT, transurethral resection of bladder tumor; VI-RADS, vesical imaging reporting and data system.

## CONFLICT OF INTEREST

There are no conflicts of interest.

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