Is high accuracy of Vesical Imaging-Reporting and Data System (VI-RADS) sufficient for its implementation in the urological practice?

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Aims. Currently, the only method used to differentiate between MIBC and NMIBC is transurethral resection of the bladder tumour (TURBT). Magnetic resonance and Vesical Imaging-Reporting and Data System (VI-RADS) would allow for discrimination between NMIBC and MIBC. We evaluate the sensitivity and specificity of VI-RADS in the diagnosis of muscle-invasive bladder cancer and discuss its value in everyday urological practice.

Methods. 64 patients with bladder cancer (BC) were enrolled into this prospective study. Multiparametric magnetic resonance imaging (mpMRI) was performed before transurethral resection of the bladder tumour (TURBT) and evaluated using the VI-RADS score. Score were compared to histopathology results. We evaluated the sensitivity, specificity, positive and negative predictive value of this system using both cut-off VI-RADS ≥ 3 and ≥ 4.

Results. Sensitivity of 92.3% (95%CI: 64.0; 99.8), specificity of 81.4% (95%CI: 69.1; 90.3), positive predictive value of 52.2% (95%CI: 30.6; 73.2) and negative predictive value of 98.0% (95%CI: 89.1; 99.9) was determined using cut off VI-RADS ≥ 3, while sensitivity of 76.9% (95%CI: 46.2; 95.0), specificity of 91.5% (95%CI: 81.3; 97.2), positive predictive value of 66.7% (95%CI: 38.4; 88.2), and negative predictive value of 94.7% (95%CI: 85.4; 98.9) was determined using cut-off VI-RADS ≥ 4. Based on our results, we consider the optimal cut-off point to be VI-RADS ≥ 3 with the overall prediction accuracy of 83.3% (95%CI: 72.7; 91.1).

Conclusions. We acknowledge that mpMRI provides valuable information with regard to BC staging, however, despite its high overall accuracy, we do not consider the VI-RADS could replace TURBT in discrimination between non-muscle invasive and MIBC.

Key words: bladder cancer, diagnostics, haematuria, magnetic resonance imaging

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INTRODUCTION

In the European Union, the age-adjusted incidence of bladder cancer (BC) is 20.0 and 4.6 per 100,000, in men and women, respectively. Non-muscle invasive bladder cancer (NMIBC) is diagnosed in approximately 75% of cases. The 5-year cancer-specific survival (CSS) rate for patients with NMIBC is 85–98 %. CSS in patients with the T2 stage is 68% and in patients with the T3 stage of the disease it is 25–30 % (ref.[1]). Treatment of this disease depends on staging, and early and precise discrimination between NMIBC and muscle-invasive bladder cancer (MIBC) is essential[2].

Currently, the only method used to differentiate between MIBC and NMIBC is transurethral resection of the bladder tumour (TURBT) and subsequent histopathological examination. In addition, a second resection is mandatory in patients with high-risk BC. Secondary resection has been documented to detect muscle infiltration in more than 32% of tumours, initially classified as NMIBC (ref.[3]).

In 2018, the VI-RADS score based on multiparametric magnetic resonance imaging (mpMRI) was introduced with the aim of creating a reliable and non-invasive tool for discrimination between NMIBC and MIBC (ref.[4,5]). This potentially would spare some patients from TURBT, reducing complications, reducing the time to initiation of definitive treatment, and eliminating the need for a second resection in individuals with high-risk tumours.

Recently, several studies have been published evaluat-

ing the reliability and clinical applicability of VI-RADS. More than two-thirds of the studies were retrospective[6,7].

The purpose of our study was to evaluate the reliability of VI-RADS prospectively with the main focus on the differentiation between NMIBC and MIBC and the contribution of this score to clinical practice, from the urologist's point of view.

METHODS

This prospective study was conducted at single tertiary academic centre in accordance with the principles of the Declaration of Helsinki, World Medical Association and Good Clinical Practice. The study protocol, patient information and informed consent forms were approved by independent Institutional Review Board of University Hospital Ostrava (n. 380/2020).

Study population

Between March 2020 and December 2021, we consecutively enrolled patients with a BC diagnosed by cystoscopy, ultrasound, or computed tomography. Patients with severe renal failure, claustrophobia, or other contraindications to mpMRI were excluded from the study. A total of 72 BCs were diagnosed in 64 patients. The baseline characteristics of the patients enrolled into the study are listed in Table 1.

After signing informed consent, all patients underwent mpMRI. The exam was evaluated by a single radiologist with 20 years of experience in this field. Subsequently, all patients underwent TURBT. We separately examined tumour and underlying bladder wall. We made reTURBT in case of absence of detrusor muscle in specimen, except of non-invasive papillary carcinoma, low grade. Based on the result of histological evaluation, 8 of them were referred to reTURBT according to the EAU guidelines[1.] Histology was evaluated by a single pathologist experienced in urological malignancies. All results were confirmed by an experienced pathologist from another academic institution.

Table 1. Patients and tumours' characteristics.

	Median (IQR) or n (%)[a]
Sex (female)[b]	23 (34)
Age (years)	68 (62; 75)
Bladder volume (mL)	165 (100; 283)
Tumour size (mm)	17 (12; 29)
VI-RADS[c]	
1	17 (24)
2	32 (44)
3	8 (11)
4	4 (6)
5	11 (15)

[a]the median and the interquartile range (IQR) or the absolute and relative frequencies (in %); [b]based on the number of patients (n=64); [c]based on the number of tumours (n=72).

MR examination technique

The examinations were performed on a 1.5 T instrument (Magnetom Avanto, Siemens, Erlangen, Germany, SW version Syngo B 19). A four-channel body coil was used. The patients drank 500–1000 mL of pure water 1–2 h before examination and did not urinate according to the VI-RADS recommendations[8]. Multiparametric MR consisted of a T2 TSE weighted image in three anatomical planes (TSE – turbo spin echo), DWI, and DCE. Infiltration of the uretheral meatus did not exclude the patient from the cohort; tumour invasion of the distal urether has not been specifically evaluated in VI-RADS (ref.[9]).

The TSE-weighted T2 sequence was performed at three anatomical levels: coronal, sagital, and transversal. TE was determined to be 91 ms, TR 2160 ms (using the Resolve pulse), GRAPPA 2. The matrix resolution was set at 1x0.8 mm, layer width 3 mm, and gap 0%.

3D sequences have not been used for possible problems with reduced tissue contrast[10].

The DWI sequence was adjusted according to the T2 weighted transverse sequence. The basic 3 values b 0, 500 and 1000 were used, and an automatically calculated apparent diffusion coefficient (ADC) map was used. The layer width was 3 mm, gap 0. The matrix was set at 1.8x1.6 mm. TE 90 ms, TR 3300 ms, GRAPPA 2.

DCE was performed in 2D technique T1 vibe (Siemens) with resolution 1x1 mm, layer width 2 mm. TE 2 ms, TR 5.34 mm, GRAPPA 3. The time resolution was set at 25 s.

Six consecutive measurements were made.

Pathology specimen

After fixation in 10% buffered formalin, the samples were processed in a standard manner on a SAKURA VIP6 machine (Sakura, Japan, Nagano) and embedded in paraffin. Three μm thick sections were prepared from paraffin blocks, stained with hematoxylin-eosin and Periodic Acid-Schiff (PAS). Two-step immunohistochemistry in a Ventana Benchmark Ultra (Ventana Medical System, Inc., Arizona, USA) was used to detect cytokeratin positive structures (Zytomed, MSK019, cl. AE1/AE3).

Statistical analysis

Numerical variables are presented as the median and interquartile range (IQR, i.e., the lower and upper quartiles). Categorical variables are presented using absolute and relative frequencies in percentages. The diagnostic accuracy of the VI-RADS was evaluated with the ROC curve and the optimal cut-off value was estimated. For selected cut-off values, the measures of diagnostic accuracy were evaluated, i.e., the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and overall accuracy, all characteristics were reported with their 95% confidence interval (95% CI). The significance level was set to 0.05. Appropriate statistical tests were ap-

plied if relevant. Statistical analysis was performed using R software (version 4.1.1, www.r-project.org).

RESULTS

The median age of the patients was 68 (IQR 62; 75) years. The median bladder volume during mpMRI examination was 165 mL. Two tumours were found in 8 patients. Each tumour was assigned a VI-RADS score and examined using histological examination. The median tumour size was 17 mm (5–67 mm, IQR 12; 29). Histological examination revealed urothelial carcinoma in 68 tumours (95%), squamous cell carcinoma in 2 (3%), adenocarcinoma in 1 (1%) and inverted papilloma in 1 tumour (1%).

Staging and grading of urothelial carcinoma was in the most non-invasive papillary carcinoma, low grade (54.5%). 16% urothelial carcinoma was muscle invasive. Next was non-invasive papillary carcinoma, high grade in 15% and T1 high grade in 10%. Tumours with infiltration of subepithelial connective tissues low grade were diagnosed in 3%. Concomitant carcinoma in situ (CIS) was diagnosed in 10 patients (15%). Histological examination identified one patient with only Cis (1.5%), Table 2.

Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were determined separately for cut-off values VIRADS ≥ 3 and ≥ 4. The results of the analysis are summarized in Table 3.

With the overall prediction accuracy of 83.3%, we consider optimal the cut-off value VI-RADS ≥ 3 (Fig. 1). In this case, the sensitivity is 92.3% and the specificity is 81.4%, pointing to a high rate of false positives (see Table 3). The low positive predictive value of 52.2% is due to the significantly lower prevalence of MIBC, compared to NMIBC in our set of patients.

In our data set, 55 (76%) tumours were smaller than and 17 tumours (24%) were larger than 30 mm in size. Tumours in VI-RADS ≥ 3 group compared to VI-RADS ≤ 2 group were a statistically significantly larger (Kruskal-Wallis test, P<0.001), confirming the association between the tumour size and the risk of muscle invasion (Fig. 2).

DISCUSSION

The implementation of mpMRI and the development of PI-RADS have been considered the most significant advancement in the diagnosis of prostate cancer since the introduction of a prostate specific antigen. The wide acceptance of PI-RADS led to the idea of developing a similar system, VI-RADS, which would allow for discrimination between NMIBC and MIBC. VI-RADS has been proposed to reduce the risk of understaging, particularly in high-risk patients, and reduce the need for reTURBT (ref.[11]).

Like PI-RADS, VI-RADS represents a five-point evaluation scale based on mpMRI. According to VI-RADS, tumours assigned score 1 or 2 are considered NMIBC. However, Erkoc et al. reported up to 8% incidence of MIBC in group VI-RADS 2 (ref.[11]). VI-RADS 3 represents a "gray zone", which is often considered as a cut-off for muscle invasion.

VI-RADS 4 predicts a high risk of muscle invasion, while the VI-RADS 5 score corresponds to a high probability of perivesical invasion[6].

The overall sensitivity and specificity of VI-RADS is reported to be 83% (95% CI: 70–90) and 90% (95% CI: 83–95) respectively[5]. The problem with this method remains in the determination cut-off for muscle inva-

Table 2. Staging and grading of urothelial carcinoma (n=68).

Staging and grading	%
Ta, low grade	54.5
Ta, high grade	15
T1, low grade	3
T1, high grade	10
T2	16
Only Cis	1.5
Concomitant Cis	15

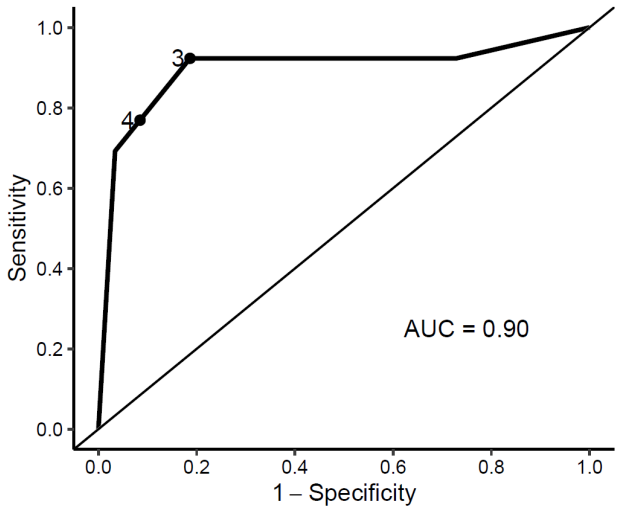

Fig. 1. Analysis of the diagnostic accuracy of VI-RADS system with the ROC curve with highlighted cut-off points at VI-RADS 3 and 4. AUC, Area under the ROC curve.

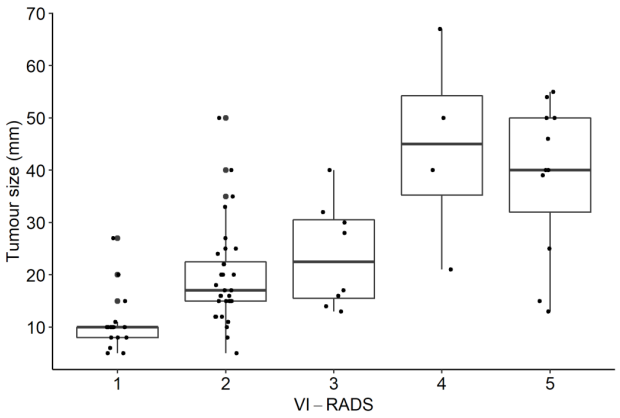

Fig. 2. Visualizing the relationship between tumour size (mm) and VI-RADS score.

Table 3. The evaluation of the diagnostic accuracy of the VI-RADS system.

	VI-RADS				
	1	2	3	4	5
MIBC	1	0	2	1	9
NMIBC	16	32	6	3	2

The values represent the absolute frequencies.

Cut-off	VI-RADS ≥ 3	VI-RADS ≥ 4
Accuracy	83.3 (72.7; 91.1)	88.9 (79.3; 95.1)
Sensitivity	92.3 (64.0; 99.8)	76.9 (46.2; 95.0)
Specificity	81.4 (69.1; 90.3)	91.5 (81.3; 97.2)
Positive predictive value	52.2 (30.6; 73.2)	66.7 (38.4; 88.2)
Negative predictive value	98.0 (89.1; 99.9)	94.7 (85.4; 98.9)

All characteristics are reported with the corresponding 95% confidence interval.

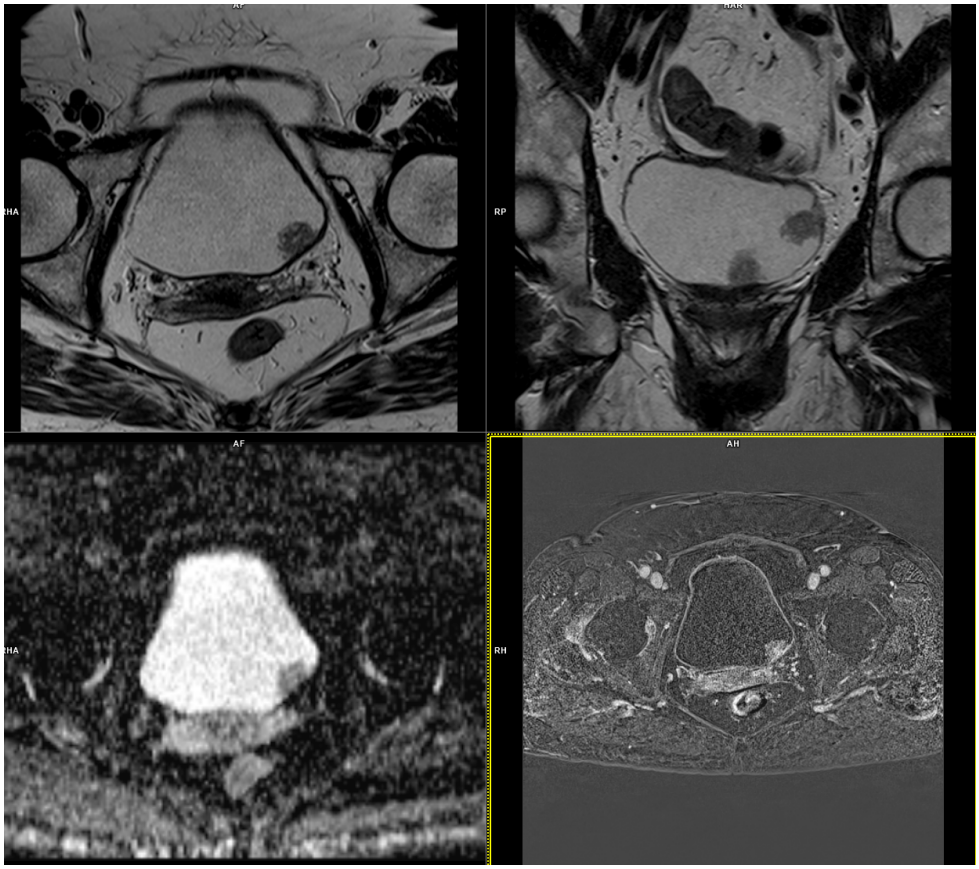

Fig. 3. VI-RADS 2 score tumour.

sion. Several studies considered a cut-off of ≥ 3 to be suggestive of muscle invasion, however others have detected a relatively high incidence of NMIBC in patients with VI-RADS 3. Therefore, the use of VI-RADS ≥ 3 as a cut-off for MIBC remains controversial[12,13]. Marchioni and other authors recommend VI-RADS ≥ 4 (ref.[14-16]). According to his meta-analysis, Luo found both values to be equivalent[17]. To address this controversy, some authors recommend using another parameter in addition to the VI-RADS. For example, Akcay recommends adding the so-called tumour contact length proposing 2 cm as a cut-off for muscle invasion[12]. Another parameter that could improve the accuracy of MIBC prediction could be the Apparent Diffusion Coefficient (ADC) value, which was reported to be significantly lower in MIBC compared to NMIBC (ref.[18]).

Four other staging systems using mpMRI for the liver, neck, breast and prostate malignancy have been successfully introduced[6]. Due to anatomical location, these organs cannot be assessed visually for a precise disease staging. In contrast to these organs, bladder cancer is easily accessible for cystoscopic examination. Cystoscopy has

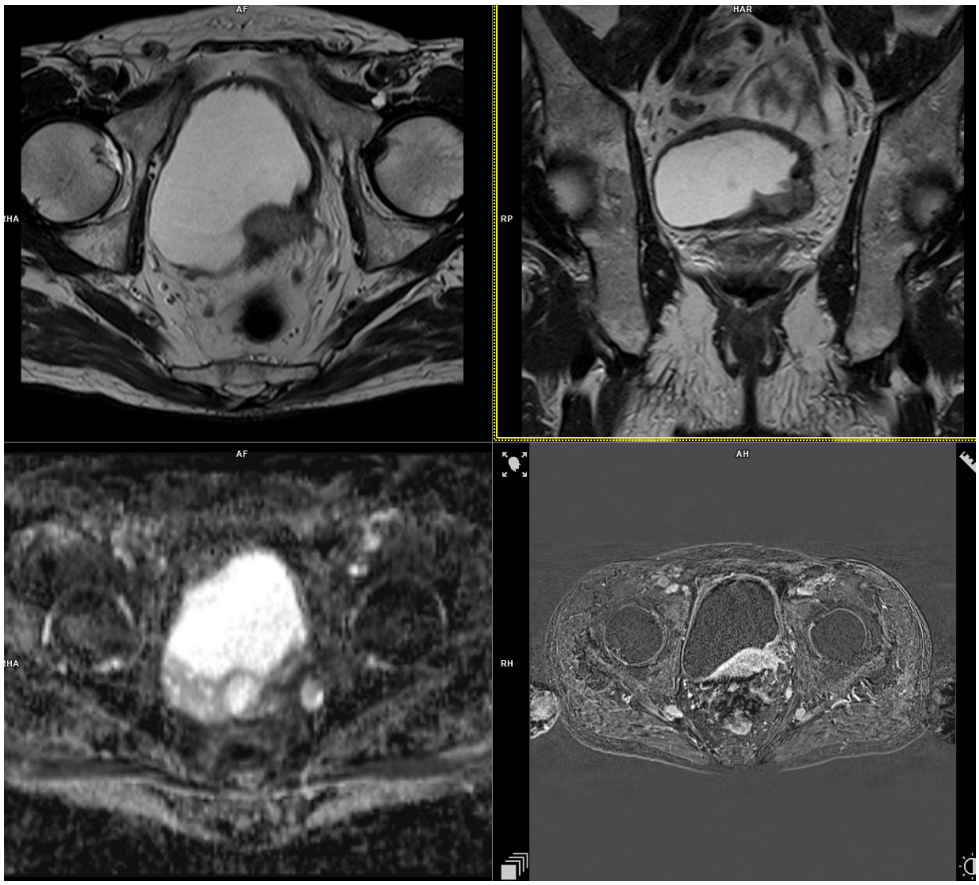

Fig. 4. VI-RADS 5 score tumour.

previously been documented to have a similar specificity and sensitivity in distinguishing between NMIBC and MIBC as VI-RADS (ref.[19]). Cystoscopy is a routine part of urological examinations, and an experienced urologist will obtain very similar information to that provided by mpMRI, in a faster and cheaper manner.

Other problems with VI-RADS are the difficulty in assessing tumours located in the trigone or bladder vertex and a low sensitivity to carcinoma in situ or lymphovascular invasion, which are very important predictors of high-risk BC (ref.[20,1]). These findings are in agreement with our data. In our cohort, histological examination confirmed carcinoma in situ in a total of 11 tumours (15%). Most of these tumours were assigned VI-RADS 1 or 2. Another significant limitation of the routine use of the VI-RADS is the need for highly experienced radiologists.

Although our data suggest that the role of mpMRI in the primary detection of MIBC is limited, we acknowledge its possible role in the evaluation of the response to treatment during neoadjuvant chemotherapy or immunotherapy and possibly other indications[21].

Currently, the spectrum of imaging methods in the diagnosis of MIBC is gradually expanding. The Diana and his group studied the possibility of determining muscle infiltration using ultrasound (high resolution microultrasound imaging – mUS). His results showed mUS could have better performance that mpMRI, but study population was small[22]. Given the availability and lower cost ultrasound potentially could replace mpMRI when it comes to distinguishing between NMIBC and MIBC.

The strengths of our study include its prospective design and appropriate size of study population. However, there are limitations to be acknowledged. These include low bladder volume during the mpMRI examination and the use of 1.5 T. According to the literature, the recommended bladder volume during the mpMRI study should be around 300 mL. Only about half of our patients were able to hold this volume, which might have affected the quality of the acquired mpMRI data. Our study used a 1.5T scanner, however, based on the existing literature, it is not clear if using a 3T scanner will increase the accuracy of the VI-RADS system significantly.

Based on our data, we believe that the role of VI-RADS in daily urological practice is rather limited. The high overall specificity and sensitivity of VI-RADS is based on excellent accuracy in the group with VI-RADS ≤ 2 tumours. Our data suggest that the VI-RADS cut off ≥ 3 gives the best accuracy, however having a closer look at the absolute numbers, we see that 75% of the patients in group VI-RADS 3 had NMIBC. This means that based on VI-RADS score a significant number of patients would be subjected to unnecessary radical cystectomy. Although mpMRI provides valuable information regarding BC staging, we believe that the VI-RADS system could not replace TURBT in determining muscle invasion.

CONCLUSION

Results of our study confirm that overall sensitivity and specificity of mpMRI and VI-RADS is high, but we believe that today this system cannot safely replace TURBT in detection of muscle invasion in bladder cancer.

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