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# Application of the VI-RADS Protocol in Urology for the Diagnosis and Treatment Planning of Bladder Cancer

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## Abstract

***Background***: Bladder cancer is one of the most common malignancies of the urinary tract, ranking tenth in terms of global cancer prevalence. Accurate diagnosis and staging are critical for determining the optimal treatment strategy. Magnetic resonance imaging (MRI) has become a key diagnostic tool, and the Vesical Imaging-Reporting and Data System (VI-RADS) was introduced to standardize MRI interpretation and improve diagnostic accuracy.

***Objective***: This study aims to evaluate the effectiveness of the VI-RADS scale in distinguishing between muscle-invasive and non-muscle-invasive bladder cancer and to explore opportunities for refining MRI protocols by incorporating advanced imaging techniques.

***Methods***: A prospective study was conducted from 2023 to 2024 at the Federal Research and Clinical Center of the FMBA of Russia, involving 68 patients with suspected bladder cancer. All patients underwent pelvic MRI followed by en bloc transurethral resection (TUR) of the bladder. VI-RADS scores were assigned based on MRI findings, and results were compared with histological examination. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated to assess the performance of VI-RADS.

***Results***: Non-muscle-invasive bladder cancer was confirmed in 42 out of 50 patients (84%) in the low-risk VI-RADS group (1-3), while muscle invasion was detected in 14 out of 18 patients (77.8%) in the high-risk group (4-5). The VI-RADS system demonstrated a sensitivity of 63.6%, specificity of 91.3%, PPV of 77.8%, and NPV of 84%, with an overall accuracy of 80.9%. Advanced imaging techniques, such as ultrafast dynamic contrast-enhanced MRI, improved di-

agnostic precision by reducing false-positive and false-negative results.

***Conclusion***: The VI-RADS system is a valuable tool for assessing bladder cancer invasion depth, with high specificity that aids in reducing unnecessary radical procedures. However, its moderate sensitivity underscores the need for a comprehensive diagnostic approach. The integration of next-generation imaging modalities and molecular markers may further enhance staging accuracy and optimize treatment strategies for bladder cancer patients.

## Introduction

Bladder cancer is among the most common malignant tumors of the urinary tract, ranking tenth in terms of prevalence among all cancer types worldwide [1]. According to the International Agency for Research on Cancer (IARC), in 2020 more than 573,000 new cases of bladder cancer were registered, along with around 213,000 deaths from this disease [1]. The incidence of bladder cancer continues to rise, especially in developed countries, primarily attributed to risk factors such as smoking and exposure to industrial chemicals [2]. In addition, genetic predisposition factors are increasingly being investigated, including hereditary aspects tied to polymorphisms in genes involved in carcinogen metabolism, which may lead to a more individualized approach to screening and therapy [3].

Accurate diagnosis and staging of bladder cancer are crucial for selecting the optimal treatment strategy and predicting outcomes [4]. Non-muscle-invasive bladder cancer (NMIBC) is typically managed by transurethral resection (TUR) followed by intravesical therapy [5]. Meanwhile, muscle-invasive bladder cancer (MIBC) requires a more aggressive approach, including radical cystectomy and systemic chemotherapy [6]. In recent years, immunotherapy, particularly checkpoint inhibitors (PD-1/PD-L1), has shown promising results in the treatment of advanced and metastatic bladder cancer [7].

Magnetic resonance imaging (MRI) of the pelvis with intravenous contrast enhancement has become an important tool in the diagnosis and staging of bladder cancer [8]. In recent years, the VI-RADS (Vesical Imaging-Reporting and Data System) scale was introduced to standardize the interpretation of MRI findings and improve diagnostic accuracy [9]. The VI-RADS system estimates the likelihood of muscle invasion using a five-point scale, where 1 indicates minimal risk and 5 represents the highest risk [9]. This approach enables clinicians to plan treatment strategies and predict outcomes more precisely [10]. Emerging data highlight the benefits of multiparametric MRI, including improved visualization and characterization of bladder tumors [8, 9, 10].

### *Recent Developments in Imaging*

Besides the classic MRI protocol (T2-weighted imaging, DWI, and conventional DCE), several contemporary studies have explored additional techniques such as ultrafast dynamic contrast-enhanced imaging (ultrafast DCE) and pseudo-morphological diffusion mapping [11]. These modalities may enhance detection of microscopic muscle invasion and reduce false-negative results. Furthermore, artificial intelligence and machine learning are increasingly being explored to enable automated and more objective analysis of MRI data, thereby minimizing interobserver variability [12].

### *Purpose of the Study*

To evaluate the effectiveness of the VI-RADS scale in distinguishing between muscle-invasive and non-muscle-invasive bladder cancer using transurethral resection and to discuss opportunities for refining MRI protocols by integrating new imaging methods.

## Materials and Methods

From 2023 to 2024, a prospective study was conducted at the Clinical Center of the Federal Research and Clinical Center of the FMBA of Russia named after Yu.M. Lopukhin, involving 68 patients with suspected bladder cancer. The cohort included 18 women (26.5%) and 50 men (73.5%), with a mean age of 62.5 years (range 45-80). Some patients had well-established risk factors, including a long-

term smoking history (>20 years) or occupational contact with industrial dyes.

### *Inclusion and Exclusion Criteria*

#### *Inclusion criteria*

- Age over 18 years.
- Presence of a bladder tumor confirmed by ultrasound or cystoscopy.
- No contraindications to MRI or TUR.

#### *Exclusion criteria*

- Previous history of bladder cancer treatment.
- Presence of other malignant neoplasms.
- Inability to undergo MRI for medical reasons.

### *Study Methods*

All patients underwent single-block (en bloc) transurethral resection of the bladder following MRI of the pelvis with intravenous contrast. Scans were performed on a 1.5 T MRI scanner using a standardized protocol recommended for VI-RADS assessment [9, 10, 11]. This included T2-weighted images in three planes, diffusion-weighted imaging (DWI), and dynamic contrast-enhanced (DCE) sequences. When technically feasible, additional ultrafast DCE sequences were utilized to improve assessment of tumor vascularization and margins.

MRI data were evaluated by two independent radiologists with 3-8 years of experience in urogenital radiology. They were aware of clinical data but blinded to histological outcomes. Each case was assigned a VI-RADS score; disagreements were resolved by consensus [12]. Based on their VI-RADS scores:

- Low-risk group (VI-RADS 1-3): 50 patients.
- High-risk group (VI-RADS 4-5): 18 patients.

All patients subsequently underwent TUR of the bladder with histological evaluation of resected tissue to determine tumor grade and depth of invasion.

### *Statistical Analysis*

To determine the effectiveness of VI-RADS in predicting muscle invasion, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Statistical analysis was performed using SPSS version 26.0. A p-value $<0.05$ was considered significant. Additionally, in a subgroup of 20 patients who underwent advanced MRI techniques (e.g., ultrafast DCE), the impact of these sequences on diagnostic accuracy was analyzed and compared with the main cohort.

## Results

### *Demographic Data and Tumor Characteristics*

The mean tumor size on MRI was 25 mm (range 10-55 mm). In the low-risk group, mean tumor size was 18 mm, while in the high-risk group it reached 35 mm ($p<0.01$). Among patients with larger tumors, strong contrast enhancement on DCE scans was commonly noted, suggesting high vascularity. In some instances, inflammatory changes in the bladder mucosa complicated differentiation between superficial lesions and muscle-invasive tumors.

### *Comparison of VI-RADS and Histological Findings*

In the low-risk group (VI-RADS 1-3), non-muscle-invasive bladder cancer was confirmed in 42 of 50 patients (84%). Muscle invasion was observed in the remaining 8 patients (16%), indicating false-negative findings.

In the high-risk group (VI-RADS 4-5), muscle-invasive bladder cancer was detected in 14 of 18 patients (77.8%). Four patients (22.2%) had non-muscle-invasive tumors, indicating false-positive results.

### *Use of Additional Imaging Techniques*

In a subgroup of 20 patients who underwent more advanced imaging sequences, false-positive results occurred in only 1 patient, while false-negative results were found in 2. This represents a modest improvement in diagnostic accuracy relative to the main cohort. More detailed analysis of vascularity and diffusion properties appears to help delineate tumor borders and detect early muscle invasion.

### *VI-RADS Performance Indicators*

- Sensitivity: 63.6% (95% CI: 46.6-78.4%).
- Specificity: 91.3% (95% CI: 81.0-96.5%).
- Positive predictive value (PPV): 77.8%.
- Negative predictive value (NPV): 84%.
- Overall accuracy: 80.9%.

### *Analysis of False-Positive and False-Negative Results*

False-positive cases in the high-risk group generally involved inflammatory edema of the bladder wall that mimicked muscle invasion on MRI [13]. False-negative findings were mostly attributed to microscopic muscle invasion undetected by routine MRI or to technical limitations [14]. Wider adoption of ultrafast DCE and artificial intelligence-based analyses may reduce such inaccuracies, although further validation in larger studies is needed [12].

## Discussion

Our results confirm the effectiveness of VI-RADS for preoperative depth assessment of bladder cancer invasion. Its high specificity (91.3%) indicates a reliable capacity to rule out muscle invasion, thereby minimizing unnecessary radical interventions [15]. Nevertheless, the moderate sensitivity (63.6%) underscores the likelihood of missing certain muscle-invasive cases when relying solely on VI-RADS. This highlights the importance of a comprehensive diagnostic strategy that incorporates clinical evaluation, MRI, and supplementary tests [16]. Combining imaging with molecular markers (e.g., those reflecting tumor aggressiveness) has also been proposed to refine staging and prognostication [17].

### *Comparison with International Data*

Our findings are consistent with international research. A meta-analysis by Wang et al. (2020) documented an average sensitivity of 88% and specificity of 79% for VI-RADS in detecting muscle-invasive disease [18]. Another study by Kim et al. (2021) reported 83% sensitivity and 90% specificity [19]. Such variability may stem from differences in MRI protocols, patient populations, and radiologist expertise. A recent review by Naso et al. (2022) found that 3 T MRI, combined with advanced imaging sequences, can further enhance staging accuracy, though it is more technologically and economically demanding [20].

### *Impact of Tumor Size*

We observed a significantly larger average tumor size in the high-risk group versus the low-risk group. This finding aligns with earlier studies indicating that bigger tumors carry an elevated risk of muscle invasion [21]. Accordingly, when lesions are large, multiparametric MRI protocols may be crucial for accurate staging.

### *En Bloc Transurethral Resection*

Performing en bloc TUR provided adequate muscle-layer sampling in 98.5% of our patients, consistent with evidence suggesting that this method improves the quality of histological material and lowers recurrence rates [22]. Additionally, resecting a single specimen allows for clearer margin assessment and precise evaluation of invasion depth, ultimately informing decisions regarding second-look resection or systemic therapies.

### *Study Limitations*

Key limitations include the relatively small sample size and single-center design. Further, the consensus-driven radiological assessment may reduce reproducibility under routine clinical conditions. To confirm these findings, larger multicenter investigations are warranted. Differences in MRI scanner specifications and protocols across institutions also highlight the ongoing challenge of standardizing VI-RADS.

## Conclusion

VI-RADS is a valuable tool for preoperative evaluation of bladder cancer, enabling reliable differentiation of non-muscle-invasive and muscle-invasive tumors. Its high specificity helps spare patients from unwarranted radical procedures. Nevertheless, moderate sensitivity necessitates a comprehensive approach to diagnosis. En bloc TUR facilitates the collection of high-quality histological samples and improves staging accuracy.

Future development should integrate next-generation imaging methods (ultrafast DCE, advanced diffusion-weighted sequences, AI-based image processing) along with molecular and biological markers of tumor aggressiveness. These advances could further enhance staging precision and guide individualized treatment, thereby improving outcomes for patients with bladder cancer.

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