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Original Article

Validation of Vesical Imaging Reporting and Data System score for the diagnosis of muscle-invasive bladder cancer: A prospective cross-sectional study

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KEYWORDS
Vesical Imaging Reporting and Data System;
Bladder tumor;
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Abstract *Objective:* Vesical Imaging Reporting and Data System (VIRADS) score was developed to standardize the reporting and staging of bladder tumors on pre-operative multiparametric magnetic resonance imaging. It helps in avoiding unnecessary repeat transurethral resection of bladder tumor in high-risk non-muscle-invasive bladder cancer patients. This study was done to determine the validity of VIRADS score prospectively for the diagnosis of muscle-invasive bladder cancer.

Methods: This study was conducted from March 2019 to March 2020 at Sawai Man Singh Medical College and Hospital, Jaipur, Rajasthan, India. Patients admitted with the provisional diagnosis of bladder tumor were included as participants. All these patients underwent a 3 Tesla mpMRI to obtain a VIRADS score before they underwent transurethral resection of bladder tumor and these data were analyzed to evaluate the correlation of pre-operative VIRADS score with muscle invasiveness of the tumor in final biopsy report.

Results: A cut-off of VIRADS $\geq$4 for prediction of detrusor muscle invasion yielded a sensitivity of 79.4%, specificity of 94.2%, positive predictive value of 90.0%, negative predictive value of 87.5%, and diagnostic accuracy of 86.4%. A cut off of VIRADS $\geq$3 for prediction of detrusor muscle invasion yielded a sensitivity of 91.2%, specificity of 78.8%, positive predictive value of 73.8%, negative predictive value of 93.2%, and accuracy of 83.7%. The receiver operating curve showed the area under the curve to be 0.922 (95% confidence interval: 0.862–0.983).

Conclusion: VIRADS score appears to be an excellent and effective pre-operative radiological tool for the prediction of detrusor muscle invasion in bladder cancer.

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1. Introduction

Bladder cancer is one of the most common genitourinary malignancies in elderly males and females with a high cost of treatment due to long follow-up [1—3]. Histologically transitional cell carcinoma is the most common type and classified into low and high grade with further stratification of high grade tumors into non-muscle-invasive and muscle-invasive tumors [4,5]. The standard treatment protocol of the bladder tumor is mainly based on the presence or absence of detrusor invasion. Non-muscle-invasive bladder cancer (NMIBC) is treated with transurethral resection of bladder tumor (TURBT) with or without adjuvant intravesical chemotherapy installation [6], whereas muscle-invasive bladder cancer (MIBC) is primarily treated with radical cystectomy if feasible with or without neo-adjuvant or adjuvant chemotherapy, palliative chemotherapy alone or chemoradiotherapy combined with TURBT as trimodal therapy in bladder preservation protocol [7].

Accurate staging of bladder tumor is via multimodal approach including clinical, radiological, and histopathological examination (HPE) after TURBT in order to reduce error from one particular test. However, all these modalities are highly operator dependent. Chances of under staging after TURBT are around 20%—25% cases dependent upon the surgeon experience [8—11]. Radiologists may disagree on the extent of muscle invasiveness [12], and pathologists may also differ on the grade and stage of the disease [4,13].

Multiparametric magnetic resonance imaging (mpMRI) is a safer tool without radiation exposure, provides better anatomical details of soft tissues and muscle invasion, and has fewer errors in staging bladder cancer [14,15]. It can be used in follow-up too but mpMRI had no unique protocol for reporting. Therefore, the Vesical Imaging Reporting and Data System (VIRADS) score was developed in 2017 by a multidisciplinary team from Europe, Asia, and North and South America for standard reporting of mpMRI and published in 2018 [16]. It is a five-point score assessing the probability of detrusor invasion in bladder cancer and has been validated by various retrospective studies [17—20]. To the best of our knowledge, only two prospective studies have validated the VIRADS score till now [21,22]. Therefore, we prospectively evaluated the accuracy of pre-operative mpMRI-based VIRADS score for the diagnosis of detrusor MIBC, considering HPE as gold standard for the differentiation of MIBC from NMIBC.

2. Patients and methods

2.1. Study population

The study was conducted in the Department of Urology and Renal Transplantation, Sawai Man Singh Medical College and Hospital, Jaipur, Rajasthan, India from March 2019 to March 2020. The study protocol was reviewed and approved by the institutional Ethics Committee and Clinical Trials Screening Committee (No. 653/MC/EC/2019 dated 16/11/2019).

2.2. Study design

It was a prospective observational cross-sectional study. The study protocol is shown in Fig. 1.

2.3. Sample size and inclusion criteria

All the patients admitted in our department with suspected bladder mass on either any radiological investigation (ultrasonography, computerized tomography scan, or magnetic resonance imaging) or diagnosed by cystoscopy (done anywhere else and referred to us without TURBT) were enrolled in the study after providing written informed consents.

2.4. Exclusion criteria

- Severely comorbid patients unfit for surgery.
- Patients with previous history of surgery, chemotherapy, or radiotherapy for bladder tumor (primary bladder tumor or any pelvic tumor infiltrating bladder).
- Patients in whom MRI was contraindicated or who did not consent.
- Patients having non-transitional cell carcinoma, variant histology or carcinoma *in situ* on HPE.
- Any patient whose biopsy suggested T1 tumor and repeat TURBT was not done or patient was lost to follow-up.

2.5. The mpMRI protocol and assessment of VIRADS score

After detailed history and clinical assessment, routine blood investigations were done along with urine cytology. All eligible patients were subjected to 3 Tesla mpMRI bladder (T2 weighted images [T2WIs], diffusion-weighted images [DWIs], and dynamic contrast-enhanced images [DCEIs]) after confirmation of adequate bladder distension. T2WIs were obtained in three different planes (axial, coronal, and sagittal), DWIs were acquired in axial plane with high b values (b = 0, 800, 1000, up to 2000 s/mm^2), and DCEIs were acquired in axial plane with a temporal resolution of 5 s. VIRADS scores (Table 1) were reported by an experienced and dedicated radiologist who had a special interest in mpMRI bladder reporting. For all the patients, only one VIRADS score was given. If any patient had multiple bladder lesions, then the highest assigned VIRADS score was noted. VIRADS score cut-offs of $\geq$3 and $\geq$4 were

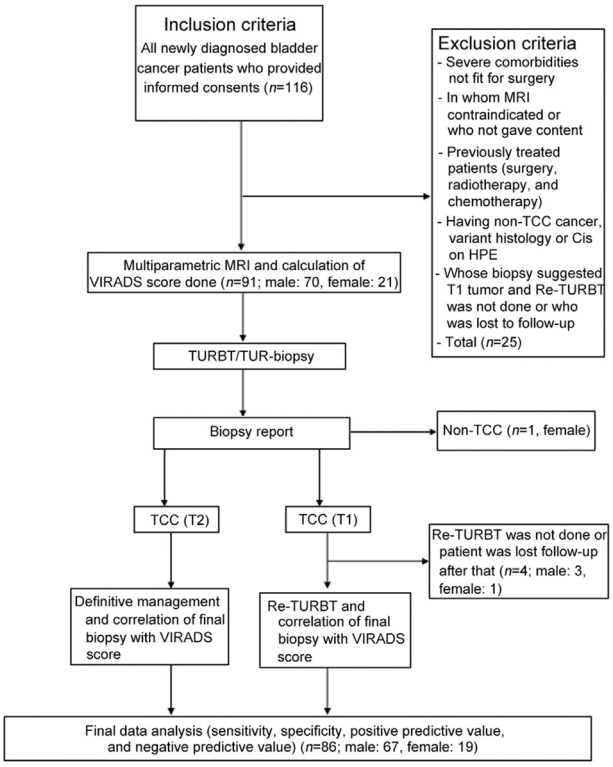

Figure 1 Protocol of the study. MRI, magnetic resonance imaging; TURBT, transurethral resection of bladder tumor; TUR, transurethral resection; TCC, transitional cell carcinoma; VIRADS, Vesical Imaging Reporting and Data System; Cis, carcinoma *in situ*; HPE, histopathological examination; Re-TURBT, repeat TURBT.

Table 1 Interpretation of VIRADS score.

VIRADS score	Likelihood of muscle invasion
1	High unlikely muscle-invasive tumor and <1 cm in size.
2	Unlikely to be a muscle-invasive tumor
3	Equivocal, there is no clear-cut evidence of muscle invasion
4	Likely detrusor invasion but no extravesical extension
5	High likely tumor invading detrusor with extension into extravesical fat

VIRADS, Vesical Imaging Reporting and Data System.

used to define muscle-invasive tumors. During the procedure, radiologist was kept unaware of clinical data.

2.6. TURBT and HPE

At our center, all patients first underwent cystoscopy, followed by TURBT with 26 Fr bipolar resectoscope under general anesthesia. During the procedure all of the following findings were noted—number, site, size of the lesions, characteristics of the tumor (papillary and sessile), presence of carcinoma *in situ*, and condition of the rest of the bladder mucosa. In case of multiple bladder tumors, size of the largest lesion was noted. After TURBT, a separate deep biopsy from the base of the tumor was taken. All the tumor specimens and deep biopsy specimens were sent in different jars to the pathology department for HPE.

Patients with biopsy report of non-muscle invasive tumor (T1) underwent repeat TURBT (Re-TURBT) after 2—6 weeks and after final histopathology, patients were managed with standard protocol (NMBIC patients were treated with or without adjuvant intravesical chemotherapy installation after TURBT and kept on regular cystoscopic surveillance, whereas MIBC patients were treated with radical cystectomy, radiation therapy, chemotherapy, or a combination depending upon the fitness for surgery and presence of metastasis and consent). Final HPEs of all the patients were correlated with pre-operative VIRADS score and all the data were collected for final analysis.

2.7. Statistical analysis

To assess the ability of the VIRADS score to predict muscle invasiveness of bladder tumors, statistical analysis was performed using the SPSS® Statistics 24 (IBM Corp., SPSS Statistics for Windows, Version 24.0. Armonk, NY, USA). Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were measured. The receiver operating curve was plotted and area under curve (AUC) was calculated. VIRADS scores of 3 and 4 were used as cut-off value for the prediction of detrusor muscle invasion. A p-value of <0.05 was considered statistically significant.

3. Results

The study initially enrolled 116 patients including 89 (76.72%) males and 27 (23.28%) females in male to female ratio of 3.30, with a mean age of 64.5 years (range 36.0—82.0 years). All 116 (100%) patients had a history of gross hematuria at presentation and 106 (91.38%) were chronic smokers. Out of these, 25 (19 males and 6 females) patients were excluded from analysis because of the inability to undergo MRI (significantly deranged renal function test, claustrophobia, or presence of prosthesis) or were unfit for general anesthesia. Therefore, a total of 91 (78.44%) underwent mpMRI and TURBT. After TURBT, one (0.86%) female patient was excluded because of adenocarcinoma on HPE and four patients (3.45%; three males and one female) were excluded as lost to follow up.

Finally, only 86 patients (67 males and 19 females) were available for final analysis. Out of these 86 patients, 14 (16.28%) patients had VIRADS score 1; 30 (34.88%) patients had VIRADS score 2; 12 (13.95%) patients had VIRADS score 3; 15 (17.44%) patients had VIRAD score 4; and rest 15 (17.44%) patients had VIRADS score 5. Urine cytology report was positive in 22 (25.58%) patients. During routine cystoscopy before TURBT, we found a single lesion in the bladder in 61 (70.93%) patients and multiple lesions in 25 (29.07%) patients. Radical cystectomy was done in 6/86 (6.98%) patients (five males and one female); partial cystectomy was done in 2 (2.33%) patients (both males); and complete TURBT was done in 60 (69.77%) patients. Final biopsy was muscle suggestive of muscle-invasive tumors in

34 (39.53%) patients and non-muscle-invasive tumors in 52 (60.47%) patients. A total of 18 (20.93%) of our patients were referred for chemoradiotherapy after TURBT, because of the advanced local stage (tumor infiltrating pelvic muscles, pelvic side walls or surrounding viscera) or unwilling for radical cystectomy. A total of 8 (9.30%) patients had metastatic disease and were referred for systemic chemotherapy after TURBT. The low-grade tumors were present in 38 (44.19%) patients and high-grade tumors were seen in 48 (55.81%) patients. None of our patients had carcinoma *in situ* or variant histology on histopathology (Table 2).

A cut-off of VIRADS $\geq$4 for prediction of detrusor muscle invasion yielded a sensitivity of 79.4%, specificity of 94.2%, PPV of 90.0%, NPV of 87.5%, and diagnostic accuracy of 86.4%. A cut-off of VIRADS $\geq$3 for prediction of detrusor muscle invasion yielded a sensitivity of 91.2%, specificity of 78.8%, PPV of 73.8%, NPV of 93.2%, and accuracy of 83.7%. The receiver operating curve and AUC (0.922; 95% confidence interval [CI]: 0.862—0.983) are shown in Fig. 2.

One example case of VIRADS score 4, in a 64-year-old male patient with right posterior-lateral urinary bladder wall mass, is shown with both mpMRI images of different sequences and HPE pictures (Fig. 3 and supplementary Fig. 1).

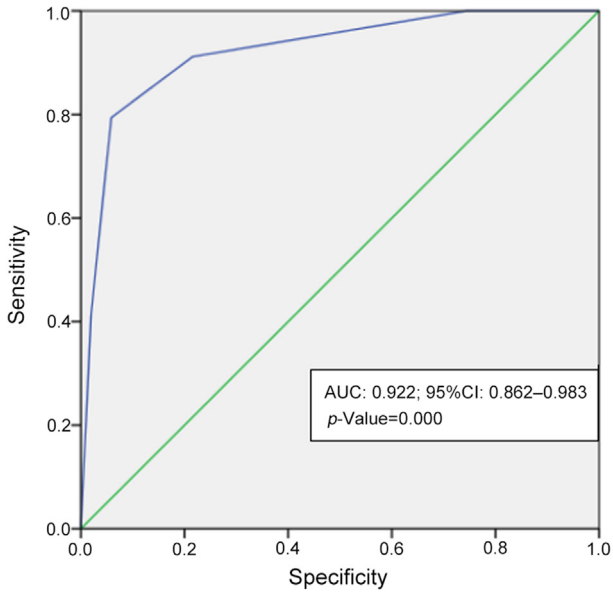

Figure 2 The receiver operating curve. AUC, area under curve; CI, confidence interval.

4. Discussion

There is a continuous increase in the incidence of bladder malignancy worldwide making it one of the leading genitourinary cancers [23]. Bladder tumor is known for multifocality and high recurrence rate; there are different management protocols based on detrusor muscle invasion; therefore, an accurate T staging is important for better management and patient care [24].

Currently, computerized tomography scan is used mainly for pre-operative staging of bladder tumors with added radiation exposure. Gold standard diagnosis is based on biopsy report after TURBT, but sometimes it is very difficult to know the exact status of detrusor invasion from report because of incomplete procedure (large, multiple tumors, intra-operative complications, or an inexperienced surgeon) or even absence of muscle in the specimen. Therefore, a large disparity exists and there is no single pre-operative tool that is perfectly accurate to distinguish detrusor muscle invasion.

Recently, MRI has been used for local staging of bladder tumor in pre-operative setting and shown promising results, especially mpMRI using T2WI, DWI, and DCEI protocols, but without a definitive standard reporting system throughout the world; therefore, VIRADS score was developed in an attempt to standardize reporting of MRI and effective patient management. In our institution, Prostate Imaging and Reporting Data system Score was routinely used for reporting of mpMRI prostate for suspected prostate cancer, but VIRADS was used for the first time for reporting of mpMRI for bladder tumors.

In our study, all 14 (100%) patients with VIRADS score 1 had a NMIBC on biopsy. Twenty seven (90.00%) patients out of a total of 30 patients with VIRADS score 2 had a non-muscle invasive tumor on biopsy while the remaining 3 (10.00%) showed muscle invasion on the final biopsy. Out of 12 patients with VIRADS score 3, 4 (33.33%) had muscle-invasive and 8 (66.67%) had non-muscle-invasive tumors. A

Table 2 Results of the present study.

Patients, characteristic	Value	VIRADS 1	VIRADS 2	VIRADS 3	VIRADS 4	VIRADS 5
Sex, *n* (%)						
Male	67 (77.91)	10 (11.63)	24 (27.91)	10 (11.63)	12 (13.95)	11 (12.79)
Female	19 (22.09)	4 (4.65)	6 (6.98)	2 (2.33)	3 (3.49)	4 (4.65)
Diameter of tumor, *n* (%)						
$\leq$3 cm	47 (54.65)	14 (16.28)	23 (26.74)	5 (5.81)	3 (3.49)	2 (2.33)
>3 cm	39 (45.35)	0	7 (8.14)	7 (8.14)	12 (13.95)	13 (15.12)
Grade of tumor, *n* (%)						
High	48 (55.81)	1 (1.16)	10 (11.63)	8 (9.30)	14 (16.28)	15 (17.44)
Low	38 (44.19)	13 (15.12)	20 (23.26)	4 (4.65)	1 (1.16)	0 (0)
Non muscle invasive, *n* (%)	52 (60.47)	14 (16.28)	27 (31.40)	8 (9.3)	2 (2.32)	1 (1.16)
Muscle invasive, *n* (%)	34 (39.53)	0	3 (3.49)	4 (4.65)	13 (15.12)	14 (16.28)

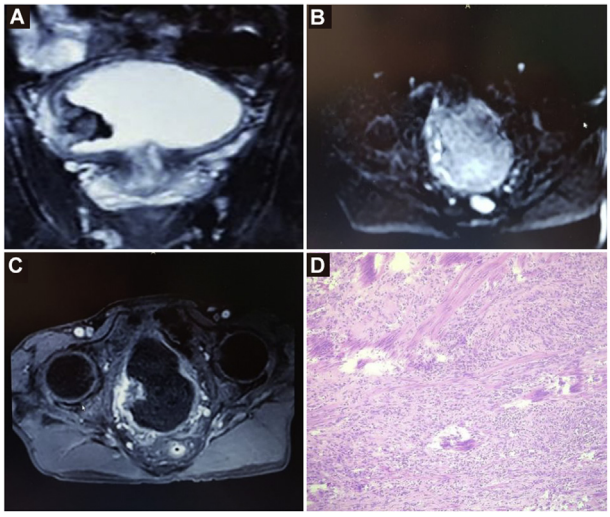

Figure 3 mpMRI images of different sequences and HPE picture of a case of VIRADS 4 (in a 64-year-old male patient with right posterior-lateral urinary bladder wall mass). (A) T2WI (axial) showing a tumor with intermediate signal intensity arising from the right postero-lateral bladder wall; (B) DWI (b = 1000 s/mm^2) showing the tumor as having hyperintense signal intensity with an irregular outline; (C) DCEI showing tumor enhancement with contrast; (D) HPE (100×) after TURBT showing high grade transitional cell carcinoma infiltrating the muscularis propria of the urinary bladder. DCEI, dynamic contrast-enhanced image; DWI, diffusion weighted image; T2WI, T2 weighted image; TURBT, transurethral resection of bladder tumor; VIRADS, Vesical Imaging Reporting and Data System; mpMRI, multiparametric magnetic resonance imaging; HPE, histopathological examination.

total of 13 (86.67%) patients out of total 15 with VIRADS score 4 had muscle invasion and 2 (13.33%) had no muscle invasion on HPE. Among 15 patients with VIRADS score 5, 14 (93.33%) patients had muscle invasion while 1 (6.67%) was free from muscle invasion on the final biopsy.

In our study, results suggested that in patients with VIRADS score 3, the ratio of muscle-invasive to non-muscle-invasive tumor was 1:2, so it's difficult to determine the exact depth of invasion pre-operatively, but in rest of VIRADS scores, there was good accuracy for the prediction of muscle invasion.

It is evident from the above observation that in selected cases where we encountered VIRADS score of 4 or 5 in pre-operative setting, our target should only be biopsy of the tumor with adequate depth because of very high possibility of muscle invasion and these patients will be the candidates for radical cystectomy in future. Therefore, after validation of the VIRADS score, these patients can get earlier neo-adjuvant chemotherapy and radical cystectomy without delay, preventing morbidity and saving the cost of Re-TURBT.

At the same time, in patients with VIRADS score 1 or 2, there are little chances of muscle invasion; therefore, our aim should be complete TURBT and these are the cases that most probably undergo multiple Re-TURBTs routinely in the current scenario. Therefore, after validation of VIRADS score in multiple studies, unnecessary Re-TURBT can be avoided with these low-risk patients and earlier intravesical chemotherapy can be started if MRI strongly suggests non-muscle-invasive tumors.

A cut-off of VIRADS ≥4 for prediction of detrusor muscle invasion yielded a sensitivity of 79.4%, specificity of 94.2%, PPV of 90.0%, NPV of 87.5%, and diagnostic accuracy of 86.4%. A cut-off of VIRADS ≥4 for prediction of detrusor muscle invasion yielded a sensitivity of 91.2%, specificity of 78.8%, PPV of 73.8%, NPV of 93.2%, and accuracy of 83.7%. The receiver operating curve and AUC (0.922; 95% CI: 0.862–0.983) are shown in Fig. 2.

A prospective study by Del Giudice et al. [21] used a cut-off of VIRADS ≥3 to predict muscle invasion and reported sensitivity, specificity, and AUC were 91.9% (95% CI: 82.2%–97.3%), 91.1% (95% CI: 85.8%–94.9%), and 0.94 (95% CI: 0.91–0.97), respectively. Although their sample size (n = 231) for final analysis was higher than us (n = 86), sensitivity and AUC of the present study while using cut-off of VIRADS ≥3 were comparable to them, with our specificity inferior to them (91.1% *vs.* 78.8%).

Marchioni et al. [22] used a cut-off of VIRADS ≥4 to differentiate MIBC from NMIBC and reported sensitivity, specificity, and AUC of 85.7% (95% CI: 57.1%–100.0%), 86.9% (95% CI: 78.7%–95.1%), and 93% (95% CI: 85%–99%), respectively, but with a smaller sample size (n = 38) for final analysis. Our study had better specificity (94.2% *vs.* 86.9%), but a poorer sensitivity (79.4% *vs.* 85.7%) compared to them while using VIRADS cut-off score ≥4.

In a retrospective study by Ueno et al. [19], a cut-off value of VIRADS ≥3 used to predict muscle invasion had sensitivity, specificity, and AUC of 88%, 77%, and 0.90 (95% CI: 0.87–0.93), respectively; but a cut-off value of VIRADS ≥4 used to predict muscle invasion had sensitivity, specificity, and AUC of 76%, 93%, and 0.90 (95% CI: 0.87–0.93), respectively. Their sample size for final analysis was small (n = 74) compared to our study, even though our observations were quite similar to them for both the cut-off values.

Another retrospective analysis by Wang et al. [20] which used VIRADS ≥3 to denote muscle invasion, reported sensitivity, specificity, and AUC of 87.1% (95% CI: 78.0%–93.0%), 96.5% (95% CI: 93.0%–98.0%), and 0.94 (95% CI: 0.90–0.98), respectively. Although they had a higher number of the patients (n = 340) for final analysis, our results were comparable to their study.

5. Limitations of study

- It was a single institute experience with a small sample size; therefore, it's difficult to generalize the results, and a multicentric study with a larger sample size is desirable.
- mpMRI is costly, not easily available and has a higher learning curve for VIRADS scoring.
- mpMRI is not useful in carcinoma *in situ* cases.

6. Conclusion

We concluded that VIRADS score is a good, easy to interpret, and applicable radiological tool for the prediction of MIBC in pre-operative setting, which can help in proper

management planning and explaining prognosis to the patients.

Author contributions

Study design: Vyas Nachiket, Priyadarshi Shivam.
Data acquisition: Kumawat Ghanshyam, Gupta Bhagwan Sahay.
Data analysis: Kumar Ashok.
Drafting of manuscript: Kumawat Ghanshyam.
Critical revision of the manuscript: Singla Mohit, Sharma Govind.

Conflicts of interest

The authors declare no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajur.2021.06.001.

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