

Abstract #: (MP55-12)

Introduction

Multiparametric magnetic resonance imaging (mpMRI) for is expanding and becoming accurate in providing high tissue contrast resolution, getting able to finely differentiate bladder wall layers. VI-RADS score is a novel diagnostic tool adopted to provide preoperative BCa staging demonstrated to be a reliable image-guided approach to assess presence of muscle invasiveness in the pre-TURBT setting. Aim of this study is to validate the diagnostic accuracy of VI-RADS scoring system in discriminating NMIBC from MIBC in a prospective single-center cohort of patients who undergo mpMRI of the bladder as initial diagnostic tool before TURBT.

Inclusion Criteria

- Primary suspicion for BCa
- no prior intravesical treatment
- Primary/Concomitant CIS no prior endovesical procedures
- - Non-urothelial BCa

Exclusion Criteria

- MR "unsafe" devices

GFR ≤ 30ml/min

Prospective validation of vesical imaging-reporting and data system (VI-RADS) for non-muscle invasive (NMI) vs. muscle invasive bladder cancer (MIBC) discrimination in patients candidate for primary transurethral resection of bladder tumors (TURBT)

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Materials and Methods

Between December 2017 and May 2019 all patients referred to our institutions for BCa suspicion were offered mpMRI before TURBT as per institution protocol. Each patient underwent mpMRI of the bladder to evaluate diagnostic accuracy of VI-RADS score in NMI-and-MIBC discrimination at initial TURBT. All exams are reviewed by two urogenital radiologists, blinded to clinical history. Both readers assign a VI-RADS score (1 to 5) to each lesion (up to three per patient) and for each patient only the one with the highest VI-RADS score is considered. A cutoff score of VI-RADS > 3 to define MIBC is assumed. Sensitivity, specificity, positive and negative predictive values (PPV, NPV) are calculated to assess accuracy of mpMRI in discriminating NMI-and-MIBC, using TURBT for LR-NMIBC (Re-TURBT) for HR-NMIBC and radical cystectomy for MIBC results as standard of reference. MpMRI performance is assessed by receiver operating characteristics (ROC) curve analysis. K statistics to estimate inter- and intra-reader variability. All patients selected for undergoing Re-TURBT due to high-risk Ta-T1 NMIBC were further

evaluated to assess the level of concordance between Re-TURBT outcomes and preoperatively determined VI-RADS scores. Dec 2017 and May 2019 Suspicious for Primary BCa (n=288) at Cystoscopy (n=179, 62.1%) Ultrasound (n=80, 27.8%) Excluded due to: CT scan (n=29, 10.1%) Impaired renal function (n=15, 5.2%) Claustrophobic disorders (n=7, 2.4%) MR "Unsafe/Conditional" devices (n=11, 3.8%) Not adequate bladder distension (n=10, 3.5%) mpMRI of the Bladder Not signed informed consent (n=9, 3.1%) VI-RADS determination (score 1 – 5) Primary TURBT & Histopathological evaluation (n=236)Non-Urothelial BCa (n=5, 2.1%) NMI-from-MIBC at TURBT | Aim 1 (whole cohort, n=231) LR-NMIBC (n= 58, 24.5%) MIBC (n= 42, 17.8%) NMIBC with CIS (n= 17, 7.2%) HR-NMIBCs (n=114) undergoing Re-TURBT Analysis of Concordance: Re-TURBT reports

Preop. VI-RADS score

Flow chart of the study

VI-RADS1: Uninterrupted low SI line representing muscularis integrity. <1.0 VI-RADS2: As VIRADS #1 but >1.0 cm and thickened inner layer. VI-RADS3: Disappearance of category 2 findings, but no clear disruption SI line suggesting extension into muscularis layer. VI-RADS 5: Extension of intermediate SI tumor to

SC#1: uninterrupted low SI line representing the integrity of muscularis propria (lesion <1 cm; exophytic tumor with VI-RADS 1 CE 1 and DWI 1 or without stalk and/or thickened inner layer) SC#2: uninterrupted low SI line representing the integrity of muscularis propria (lesion >1 cm; exophytic tumor with stalk and/or high SI thickened inner layer, when present, VI-RADS 2 CE 2 and DWI 2 or sessile/broad-based tumor with high SI thickened inner layer, when present) SC#3: lack of category 2 findings with associated an exophytic tumor without stalk, or CE 3 and/or DWI 3 VI-RADS 3 sessile/broad-based tumor without high SI thickened but with no clear disruption of low SI muscularis propria CE 4 or DWI 4 VI-RADS 4 SC#4: interruption of low SI line suggesting extension of the intermediate SI tumor tissue to muscularis propria VI-RADS 5 CE 5 and/or DWI 5 SC#5: extension of intermediate SI tumor to extravesical fat, representing the invasion of the entire bladder wall VI-RADS 4 CE 4 or DWI 4 and extravesical tissues

Schematic illustration of mpMRI appearances of VI-RADS

Schematic representation of VI-RADS scoring

A total of 231 patients were enrolled

- Sensitivity and specificity in discriminating NMI-from-MIBC at initial TURBT were 91.9% (95%CI: 82.2 - 97.3) and 91.1% (95%CI: 85.8 – 94.9) respectively
- PPV and NPV 77.5% (95%CI: 65.8 86.7) and 97.1% (95%CI: 93.3 – 99.1) respectively.
- Area under curve (AUC) was 0.94 (95%CI: 0.91 0.97).
- Inter-reader agreement was overall good (K: 0.81, 95%CI: 0.65-0.93) with only 17 cases reporting disagreement between readers.
- A total of 114 patients were considered
- Sensitivity and specificity of 85% (95% CI:62.1–96.8) and 93.6% (95% CI: 86.6–97.6), respectively, to identify patients diagnosed with MIBC at Re-TURBT.
- PPV and NPV were 74.5% (95% CI: 52.4–90.1) and 96.6% (95% CI: 90.5–99.3), respectively.
- The AUC was 0.93 (95% CI: 0.87– 0.97).

Variables, n **RADS RADS RADS RADS** RADS n=31 n=29 n=12 N. of n=37 n=122 **Patients** (16)(52.8)(13.4)(12.6)(5.2)Age (years) 69 67 Median 65 – IQR | 63 – 69 | 62 – 66 | 64 – 71 | 64 – 70 N. of Lesions Unifocal 68 (55.7) 6 (19.4) 8 (27.6) (40.5)(33.3)Multifocal 54 (44.3) 21 (72.4) (59.5)(80.6)Pathologic T 51 (41.8) 5 (16.1) Ta 10 (27) 66 (54.1) 7 (22.6) 3 (10.3) ≥ T2 5 (4.1) 26 (89.7) (61.3)Concomitant 10 (8.2) 6 (19.3) 7 (24.1)

Table 1. Patient characteristics and VI-RADS evaluation for σ bladder cancer lesions for the whole cohort (n = 231a).

VI-RADS score is a novel imaging tool leading urologist to properly differentiate patients with NMI vs. MIBC before TURBT. Future prospective, larger, multicentric trials are mandatory to definitively validate clinical reliability of VI-RADS score in pre-TURBT setting.

100 80 ensitivity Value 95% CI 91.9% 82.2 – 97.3 80 100-Specificity 100 80

20

Results

Figure 1.

Figure 2.

patients

assumed.

Criterion ≥ 3 Value 95% CI

0.93

60

100-Specificity

85% 62.1 – 96.8

93.6% 86.6 – 97.6

80

0.87 - 0.97

VI-RADS score

ROC curve representing VI-RADS score performance in discriminating NMIBC from MIBC at initial TURBT (whole cohort; n=231). Criterion ≥3 to define MIBC was assumed.

ROC curve representing

of adverse pathology

(MIBC) at Re-TURBT

(n = 114). Criterion

3 to define MIBC was

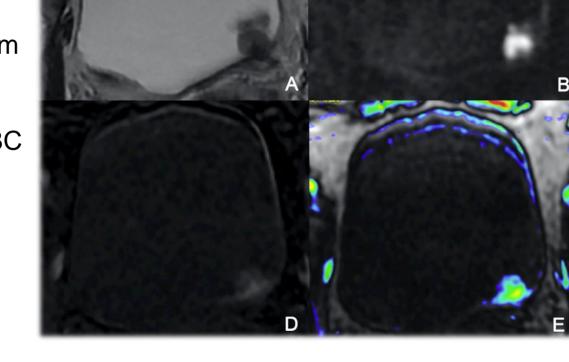


Figure 3. a) T2W imaging showed an exophytic lesion on the LL wall, > 1 cm in greatest dimension, with a low SI stalk. **b)** DWI (b = 2000) **c)** ADC map, showed an exophytic lesion with restricted diffusion

DCE imaging and e) Perfusion Map showed early enhancement of the lesion and inner layer without early enhancement of the m. propria. Overall VI-RADS score was 2. T stage after TURBT was HG-T1 while Re-TURBT resulted in absence of cancer at primary tumor site.

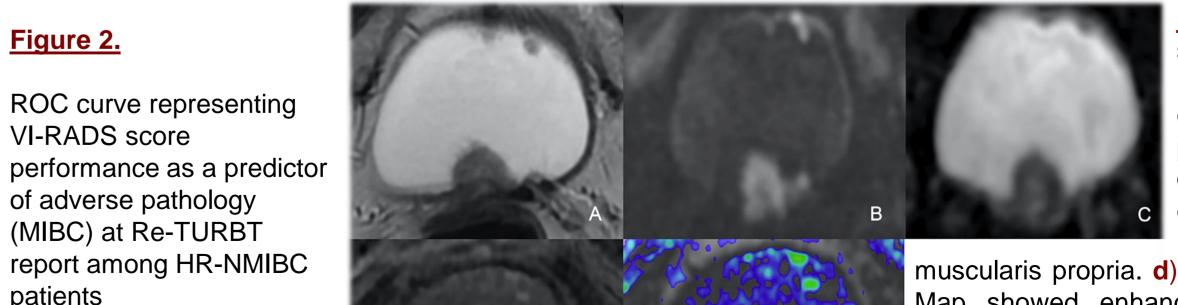


Figure 4. a) T2W imaging showed a lesion > 1 cm at the of the bladder that extends to the muscularis propria. **b**) DWI (b = 2000) and c) ADC maps showed a lesion extending through the

muscularis propria. d) DCE imaging and e) Perfusion Map showed enhancement extended through the muscularis propria. Overall VI-RADS score was 4. T stage after TURBT was HG-T1 NMIBC. Re-TURBT was performed resulted in T2 stage. The patient underwent RC and stage was confirmed to be pT2b,N0, M0.

Conclusions