



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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Introduction

Multiparametric magnetic resonance imaging (mpMRI) for bladder cancer (BCa) is expanding and becoming increasingly 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.

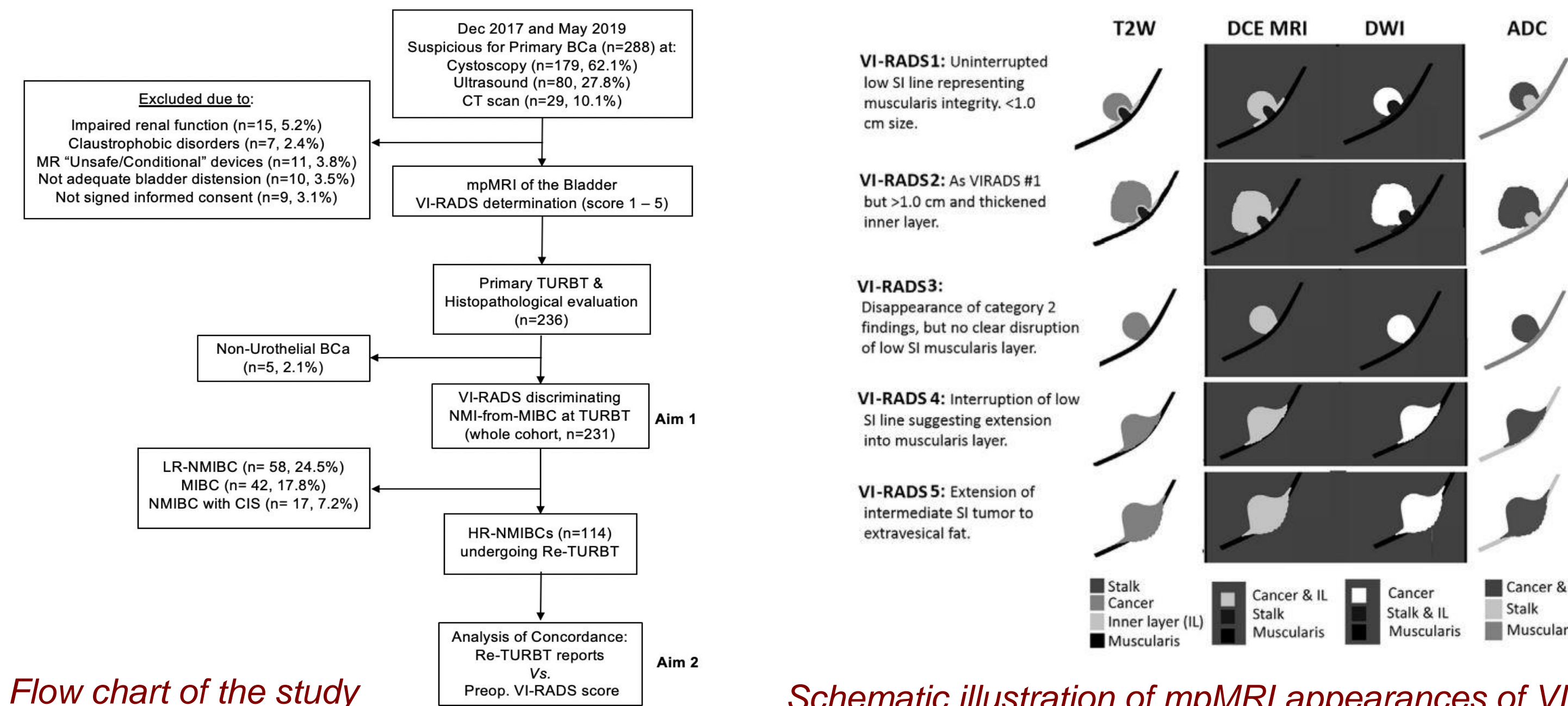
Inclusion Criteria

- Primary suspicion for BCa
- MR "unsafe" devices
- no prior intravesical treatment
- GFR \leq 30ml/min
- no prior endovesical procedures
- Primary/Concomitant CIS
- Non-urothelial BCa

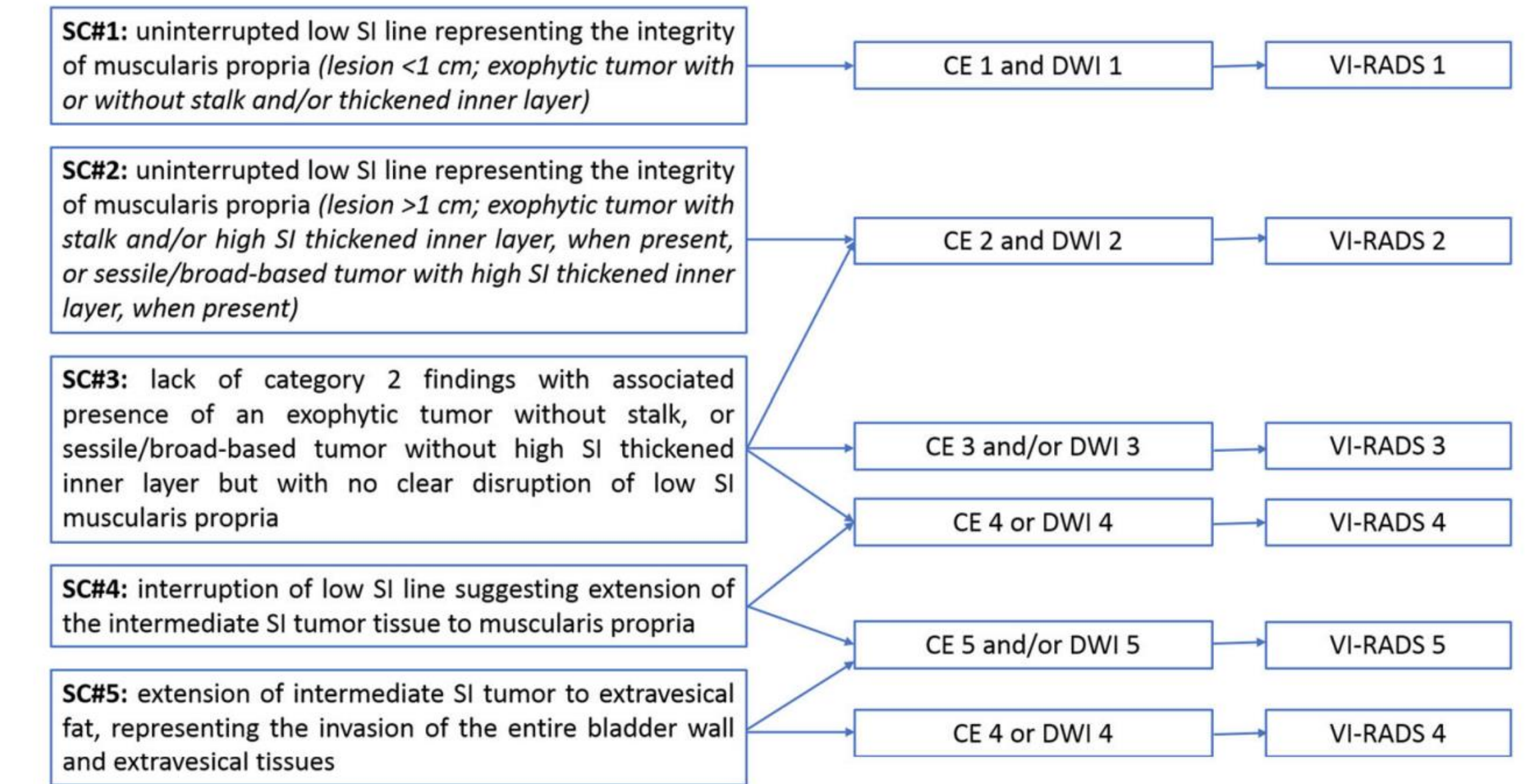
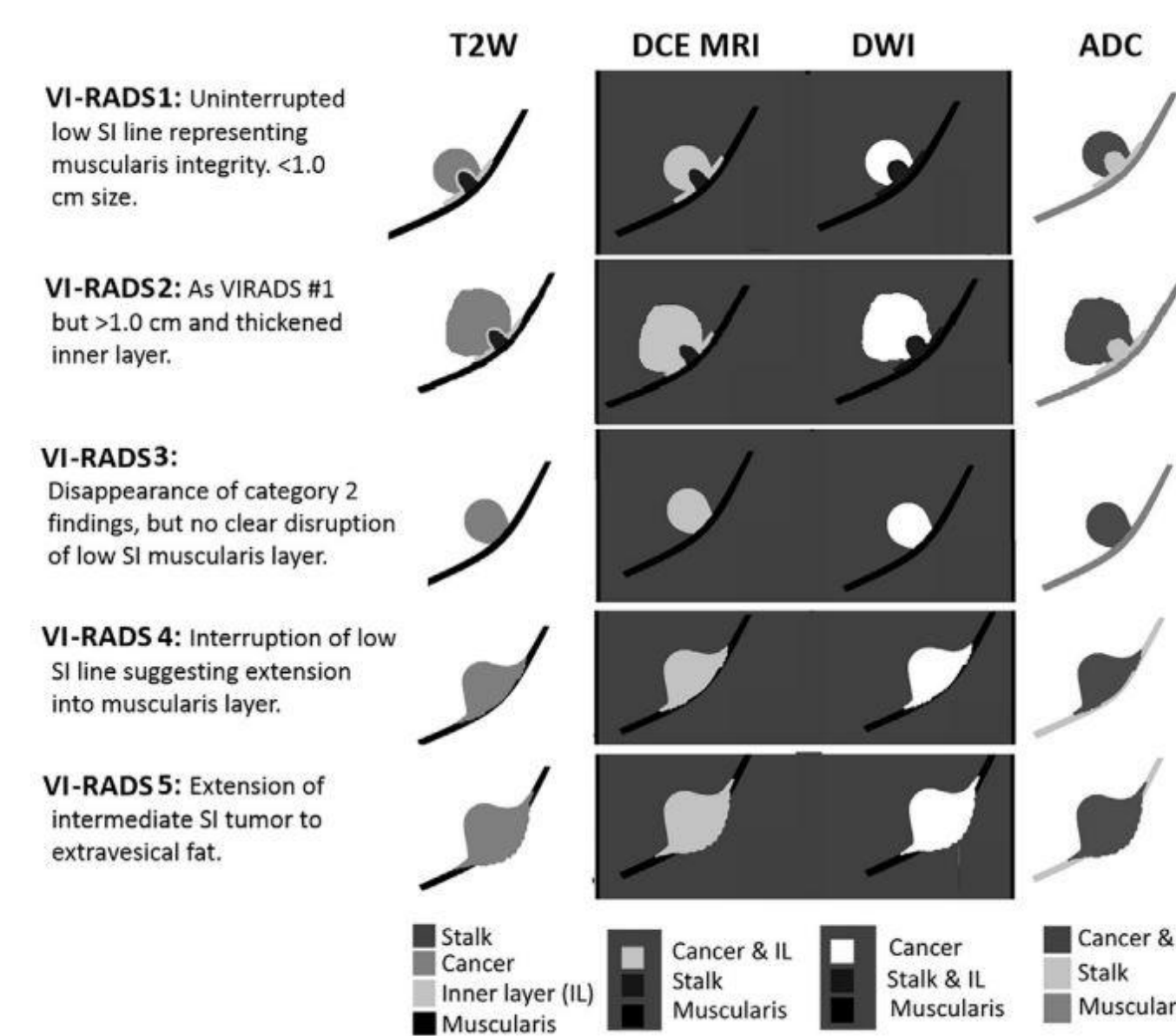
Exclusion Criteria

- 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%)
- Not signed informed consent (n=9, 3.1%)

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 \geq 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, repeated TURBT (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.



Materials and Methods



Schematic illustration of mpMRI appearances of VI-RADS

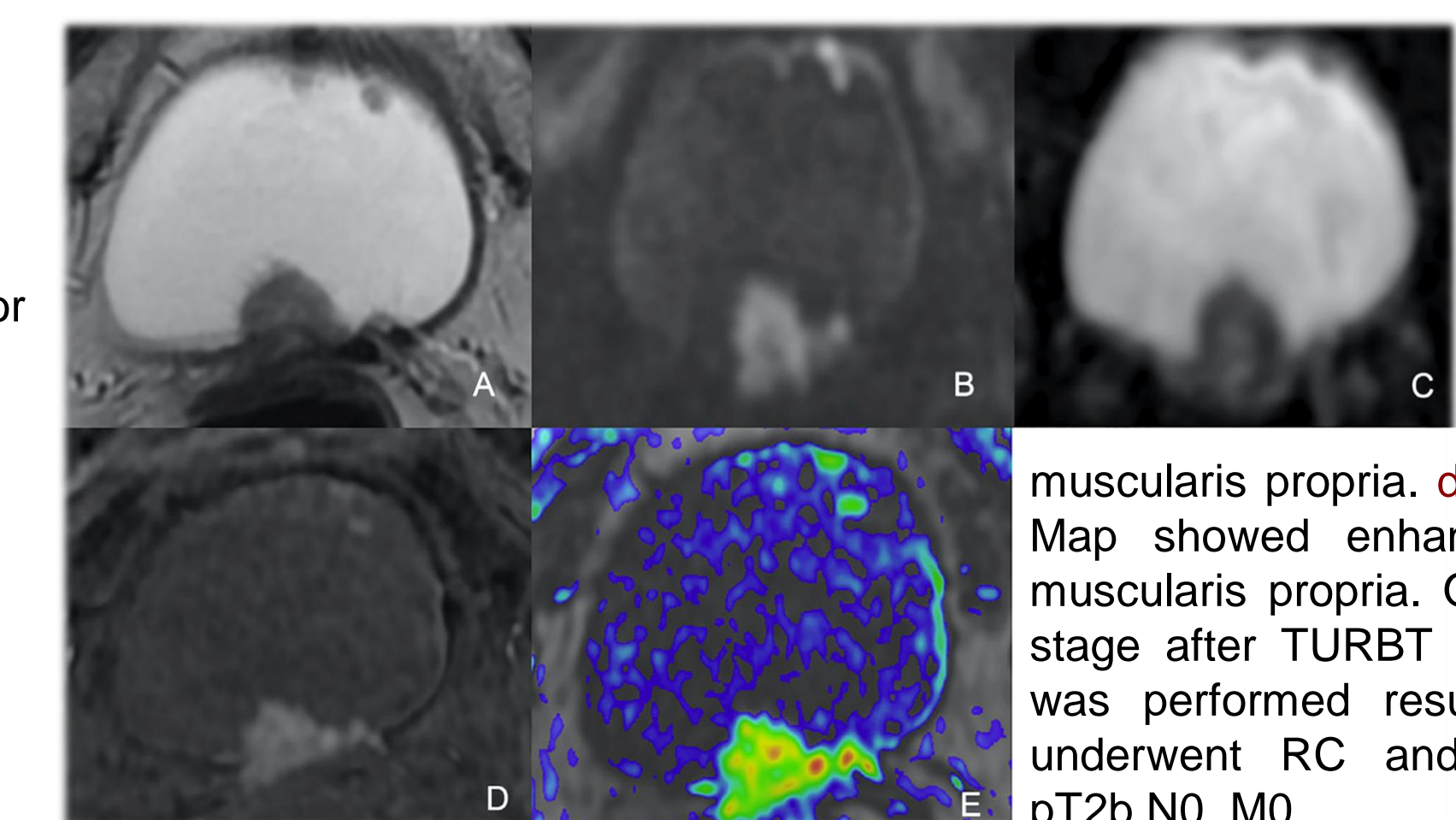
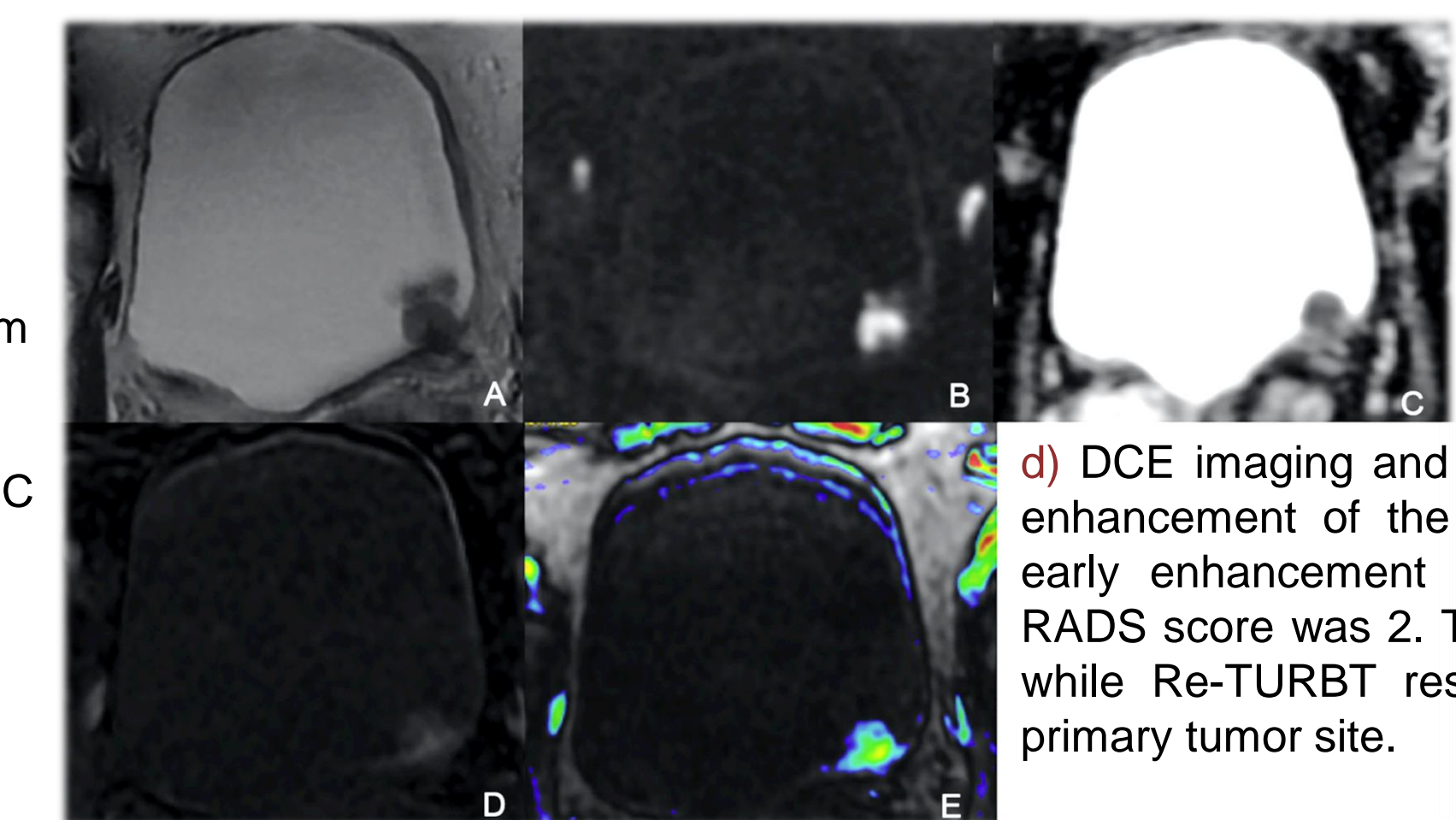
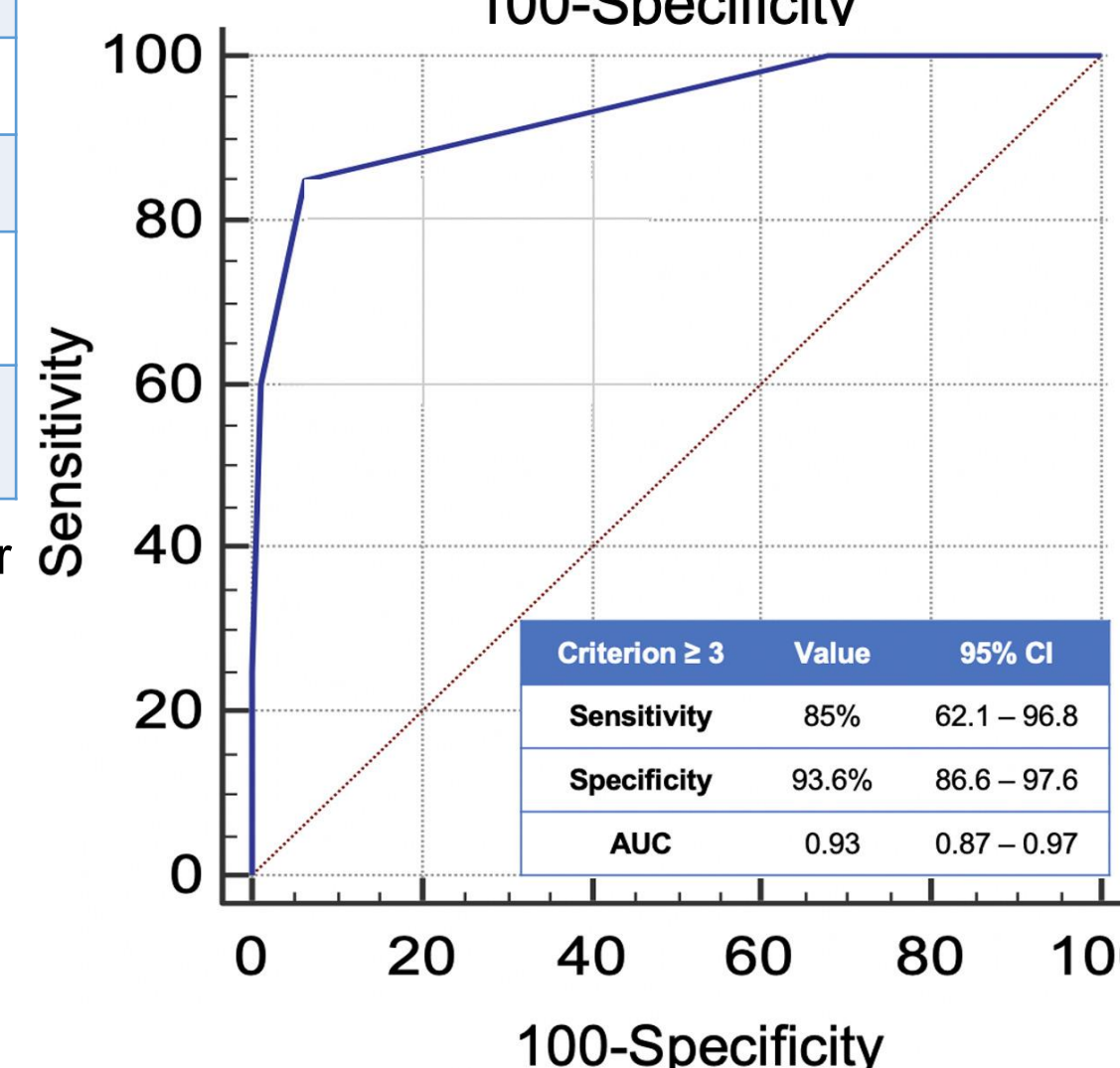
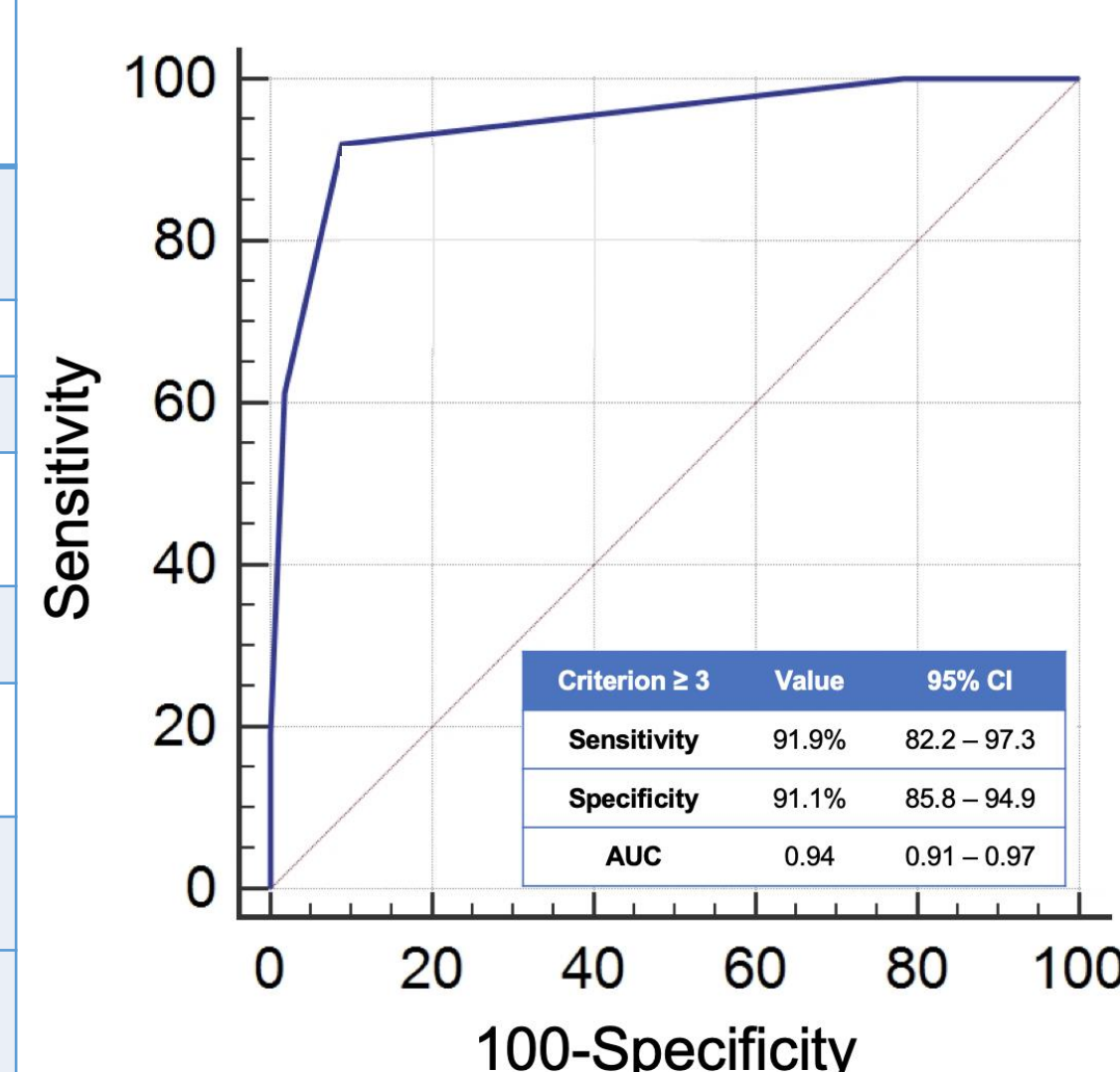
Schematic representation of VI-RADS scoring

Results

- 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 (%)	VI-RADS 1	VI-RADS 2	VI-RADS 3	VI-RADS 4	VI-RADS 5
N. of Patients	n=37 (16)	n=122 (52.8)	n=31 (13.4)	n=29 (12.6)	n=12 (5.2)
Age (years)					
Median	66	64	68	67	69
IQR	63 – 69	62 – 66	64 – 71	64 – 70	65 – 71
N. of Lesions					
Unifocal	15 (40.5)	68 (55.7)	6 (19.4)	8 (27.6)	4 (33.3)
Multifocal	22 (59.5)	54 (44.3)	25 (80.6)	21 (72.4)	8 (66.6)
Pathologic T stage					
Ta	10 (27)	51 (41.8)	5 (16.1)	0	0
T1	27 (73)	66 (54.1)	7 (22.6)	3 (10.3)	0
\geq T2	0	5 (4.1)	19 (61.3)	26 (89.7)	12 (100)
Concomitant CIS	1 (2.7)	10 (8.2)	6 (19.3)	7 (24.1)	2 (16.7)

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



Conclusions

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.