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Updated Prostate Imaging Reporting and Data System (PI-RADS) v2 versus v1: improved detection accuracy in Clinically Significant Prostate Cancer

Prostate Imaging Reporting and Data System (PI-RADS) v2 contre v1 : précision améliorée pour les cancers de prostate Cliniquement Significatifs

PESLERBE Sylvain

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Sous la direction de Madame Le Docteur NEDELCU Cosmina

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Monsieur le Professeur AUBE Christophe	Président
Madame le Docteur NEDELCU Cosmina	Directeur
Monsieur le Professeur AZZOUZI Abdel-Rahmène	Membre
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MAÎTRES DE CONFÉRENCES

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DINOMAIS Mickaël	Médecine physique et de réadaptation	Médecine
DUCANCELLE Alexandra	Bactériologie-virologie ; hygiène hospitalière	Médecine
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PENCHAUD Anne-Laurence	Sociologie	Médecine
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PIHET Marc	Parasitologie et mycologie	Médecine
PRUNIER Delphine	Biochimie et biologie moléculaire	Médecine
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SCHINKOWITZ Andréas	Pharmacognosie	Pharmacie
SIMARD Gilles	Biochimie et biologie moléculaire	Médecine
TANGUY-SCHMIDT Aline	Hématologie ; transfusion	Médecine
TRICAUD Anne	Biologie cellulaire	Pharmacie
TURCANT Alain	Pharmacologie	Médecine

AUTRES ENSEIGNANTS

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O'SULLIVAN Kayleigh	Anglais	Médecine

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Plan

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LIST OF ABBREVIATIONS

ADC	Apparent Diffusion Coefficient
CSD	Clinically Significant Disease
DCE	Dynamic Contrast Enhanced
DWI	Diffusion Weighted Imaging
EPI	Echo Planar Imaging
ESUR	European Society of Urogenital Radiology
HPS	Hematoxylin-Phloxin-Saffron
mpMRI	Multi-parametric Magnetic Resonance Imaging
MRI	Magnetic Resonance Imaging
PCa	Prostate Cancer
PI-RADS	Prostate Imaging Reporting and Data System
PZ	Peripheral Zone
T2WI	T2 Weighted Imaging
TRUS	Transrectal Ultrasound
TSE	Turbo Spin Echo
TZ	Transition Zone

TITLE

Updated Prostate Imaging Reporting and Data System (PI-RADS) v2 versus v1: improved detection accuracy in Clinically Significant Prostate Cancer.

AUTHORS

PESLERBE Sylvain, Interne en Radiologie, 4 rue Larrey, 49100, Angers, 02.41.35.36.37, s.peslerbe@hotmail.com

NEDELCU Cosmina, Docteur en Radiologie, 4 rue Larrey, 49100, Angers, 02.41.35.46.62, nedcos76@yahoo.com

BAZERIES Paul, Docteur en Radiologie, 4 rue Larrey, 49100, Angers, 02.41.35.36.37, paul.bazeries@gmail.com

COTY Jean Baptiste, Interne en Radiologie, 4 rue Larrey, 49100, Angers, 02.41.35.36.37, cotyjeanbaptiste@gmail.com

RIDEREAU-ZINS Catherine, Docteur en Radiologie, 4 rue Larrey, 49100, Angers, 02.41.35.35.02, caridereauzins@chu-angers.fr

SAULNIER Patrick, Professeur en Biostatistiques, responsable du département hospitalo-universitaire de biostatistiques et méthodologie, 4 rue Larrey, 49100, Angers, 02.41.35.64.18, Patrick.saulnier@univ-angers.fr

AZZOUZI Abdel Rahmène, Professeur en Chirurgie Urologique, Chef de service du département d'Urologie, 4 rue Larrey, 49100, Angers, 02.41.35.36.03, ARAzzouzi@chu-angers.fr

ROUSSELET-CHAPEAU Marie Christine, Professeur en Anatomopathologie, Chef de service du département de pathologie cellulaire et tissulaire, 4 rue Larrey, 49100, Angers, 02.41.35.45.61, MCRousselet@chu-angers.fr

AUBE Christophe, Professeur en Radiologie, Chef de service du département de Radiologie, Chef du Pôle Stérilisation Fonctionnel Imagerie Pharmacie, 4 rue Larrey, 49100, Angers, 02.41.35.42.81, ChAube@chu-angers.fr

ABSTRACT

Objective:

To compare the new revised PI-RADSv2 to v1 for detection of Prostate Cancer (PCa) lesions focused on Clinically Significant Disease (CSD), using histopathology as reference-standard.

Materials and Methods:

From July 2013 to August 2015, 93 consecutive patients with clinical or biological PCa suspicion were included and underwent Multi-parametric MRI before biopsy. Foci were assessed and prospectively scored according to the PI-RADSv1. 143 suspicious lesions were detected, (overall score ≥ 3), systematic and imaging fusion-guided or cognitive-guided biopsies were performed. Then, blinded from histopathological outcomes, lesions were rescored retrospectively, using PI-RADSv2. All cancer and CSD (Gleason score ≥4+3 or maximal core length ≥ 4mm) detection rates were compared by the McNemar test.

Results:

Of the 50/143 cancers diagnosed (34%), 15 were clinically significant (30%). Cancer detection rate was significantly higher with PI-RADSv2: 1) for PI-RADS overall score = 5 both in CSD (40.7% versus 26.2%, $p<0.001$) and All Cancers (81.5% versus 69.0%, $p=0.03$) and 2) for PI-RADS overall score ≥ 4 in All Cancers (56.3% versus 45.1%, $p=0.002$).

Conclusion:

The present study shows the superiority of PI-RADSv2 on v1, both in detection of significant Prostate Cancer and in better differentiation with an important decrease of lesions classified PI-RADS 3.

INTRODUCTION

Prostate cancer (Pca) is the most common cancer in men in Western countries and its incidence is expected to double by 2030, due to the ageing global population. In 2012, there were about 1.1 million new cases and 300 000 related deaths worldwide [1-2].

Recent innovations in Magnetic Resonance Imaging (MRI) technology with both anatomical and functional sequences have improved tumor detection, characterization and grading. In parallel, untargeted Transrectal Ultrasound-guided biopsy (TRUS), without previous MRI, lacks sensitivity, with a false-negative rate close to 52% [3-4]. There reasons tend towards making multi-parametric Magnetic Resonance Imaging (mp-MRI) an increasingly common adjunctive procedure in PCa care, including T2-Weighted Imaging (T2WI), Dynamic Contrast Enhanced MRI (DCE-MRI) and Diffusion-Weighted Imaging (DWI) [5-6].

To bring standardization to the reporting of mp-MRI of the prostate in the detection of Clinically Significant Cancer (defined as Gleason score ≥4+3 or with maximal core length ≥ 4mm for targeted biopsy, according to the Epstein criteria [7]), the European Society of Urogenital Radiology (ESUR) published a unified Prostate Imaging Reporting and Data System (PI-RADS) in 2012 [8].

Several studies have already validated the first version of the PI-RADS [9-10]. However, this version had no clear recommendation concerning the assessment of the global PI-RADS score. Recent studies and clinical practice suggested that the weight of the different elements of the score should be used differently, regarding the localization of the lesion in the Peripheral Zone (PZ) or Transition Zone (TZ), and showed that dynamic-contrast sequences should be less critical than initially reported [11-12].

Therefore, the original PI-RADS score was revised and published as a second version, PI-RADSv2, by a steering committee of the American College of Radiology, The AdMeTech Foundation and the ESUR [13]. PI-RADSv2 introduced the dominant sequence concept leading to final score depending on anatomical localization of the lesion as follow: DWI for Peripheral Zone and T2WI for Transition Zone. In case of indeterminate lesion on the dominant sequence (score 3), a specific secondary sequence (positive DCE-MRI for PZ and score 5 on DWI for TZ) can upgrade the final score from 3 to 4 (Appendix 1).

The purpose of this study was to compare the new revised PI-RADSv2 to the first version of PI-RADS for the detection of PCa lesions focused on Clinically Significant Disease (CSD) using histopathology as the reference-standard.

MATERIALS AND METHODS

1. Patients and Study Design

This single institutional study was conducted with the accordance of the local ethics committee. The population sample concerned 93 consecutive patients, with clinical or biological PCa suspicion (elevated Prostate Specific Antigen levels or abnormal digital rectal examination), included prospectively from July 2013 to August 2015. They all underwent mp-MRI for PCa detection, whether being biopsy-naïve or after one or two biopsy negative series. Patients where included if they showed at least one suspicious lesion on mp-MRI, defined by a PI-RADS overall score ≥ 3. Patients with a prior diagnosis of clinically insignificant or significant PCa, treated or under active surveillance, or patients with no biopsies, were not included in this study.

First, each lesion was classified according to the first version of PI-RADS, before the further biopsy procedure. Then, for a second time, and blinded for histopathological results, all the lesions were scored retrospectively in accordance with the revised PI-RADSv2. Correlation of pathologic results with each of the versions of PI-RADS for detection performance were then compared.

2. Multiparametric MRI Protocol

From July 2013 to October 2014, MR examinations were performed using a 1.5T system (GE Excite 1.5T, GE Healthcare, Milwaukee, WI, USA), then until August 2015, patients underwent MR prostate imaging with a 3.0T imager (Siemens Magnetom 3.0T, Siemens Healthcare, Erlangen, Germany). All imaging studies were performed using a high resolution pelvic phased-array coil, without prior bowel preparation.

The imaging protocol was in accordance with the ESUR guidelines, with both morphological and functional MRI techniques [8]. First, a triplanar (axial, coronal and sagittal) T2W Turbo Spin-Echo (TSE) sequence was acquired.

Then, axial DWI was performed, using a multi-section spin-echo single-shot Echo Planar Imaging (EPI) sequence. Apparent Diffusion Coefficient (ADC) mapping was obtained using four increasing *b* values in three orthogonal directions (50, 400, 1000, 2000 s/mm^2).

Third, for DCE-MRI data acquisition, three-dimensional T1-wieghted spoiled gradient-echo sequences with fat signal suppression were executed, before and immediately after intra-venous injection of 0.1 mmol per kilogram of body weight contrast agent (Gadoterate meglumine, DOTAREM, Guerbet, Aulnay-Sous-Bois, France). It was administered with a flow

rate of 3ml/sec and followed by a 20 mL saline flush. Technical parameters are summarized in Appendix 2.

3. Image Interpretation and PI-RADS assessment

All examinations were read by the a radiologist with ten years of experience in prostate MR imaging interpretation (Nearly 500 prostate MR imaging examinations were performed per year in our institution), including one year working with the first PI-RADS assessment system, after participation in international training sessions (ESUR Teaching Course on Prostate MRI).

Every lesion suspected to be a cancer was assigned a score from 1 to 5 for each key sequence (T2WI/DWI/DCE) and was documented on the 27 sectors scheme proposed by a European consensus meeting and the ESUR [14]. DCE curves were measured with analytic software on a dedicated workstation (Advantage Workstation Windows, GE Medical System, Milwaukee, WI, USA; or SyngoVia Siemens Healthcare, Erlangen, Germany), using a region-of-interest (ROI) that was as large as possible; one throughout the lesion and another on a healthy zone, as control data (Appendix 3). Considered by literature as a strong and valid method for global assessment in v1, a summed score was applied for each lesion, weighting all sequences equally [15-16]. Overall score was determined as follow: sum score 3-4 = global score PI-RADSv1 1, sum score 5-6 = global score PI-RADSv1 2, sum score 7-9 = global score PI-RADSV1 3, sum score 10-12 = global score PI-RADSv1 4, sum score 13-15 = global score PI-RADSv1 5. Data concerning prostatic volume and maximum foci length were also compiled.

After the results of the biopsies were obtained, a second reading was performed by same reader as in v1, without knowledge of the histopathological outcomes. Lesions were classified according to the revised PI-RADS version 2 (Appendix 1 and 4). At least 2 months elapsed between the PI-RADSv1 and the PI-RADSv2 evaluation (Figure 1).

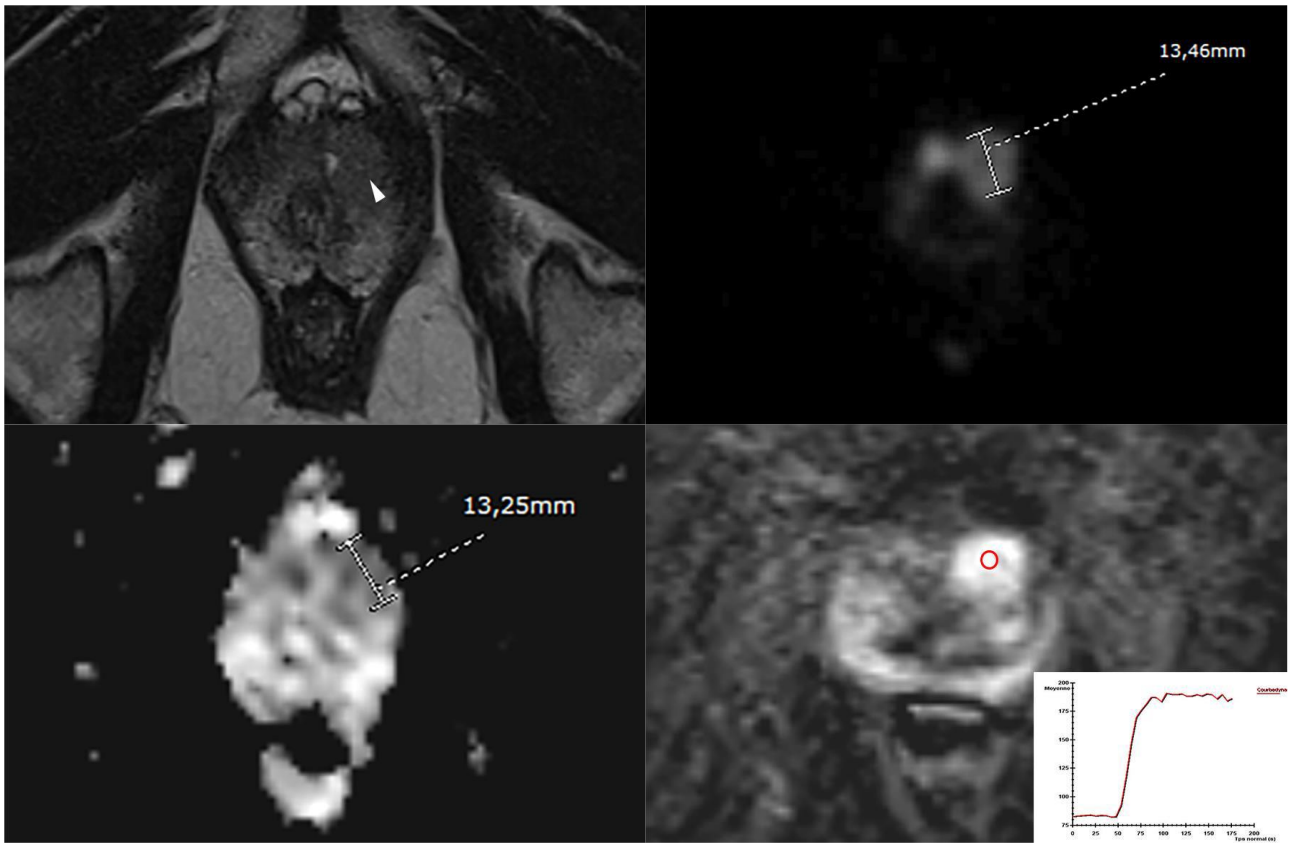

Figure 1: Example of lesion reclassification from PI-RADS v1 to v2
A: T2WI: The lesion was both scored 3 in PI-RADSv1 and v2, with intermediate appearance nor in categories ½ or 4/5 (head of arrow). ***B, C***: DWI: 13mm anterior apical lesion scored 5 in PI-RADSv1 with hypersignal on the high b-value image (b2000) and reduced ADC. Because of its length <15mm, the lesion was scored 4 according to PI-RADSv2. ***D***: DCE-MRI: focal and asymmetric enhancement of the lesion, with type 2 enhancement curve, scored 4 in PI-RADSv1 and positive in PI-RADSv2.
According to PI-RADSv2, the dominant sequence for Transition Zone lesion is T2, so the lesion was downgraded with an overall score at 3, whereas assessment score was 4 in PI-RADSv1 (mean value of DWI, T2WI and DCE-MRI score). Consequently, no biopsies are recommended on MRI alone according to the new revised PI-RADS system. Histopathology found prostatitis foci.

4. Biopsy protocol and Pathological analysis

Only lesions with PI-RADSv1 ≥ 3 were biopsied by an urologist. After antibiotic prophylactic treatment, in a single session and performed by the same operator, each patient underwent both standard 12 core TRUS-guided sextant biopsies, plus 3 to 6 targeted biopsies, according to MRI reporting and delivered schema. For 5 patients, MRI/TRUS fusion platform was used (BIOJET FUSION System and software, D&K Technologies, Barum, Germany), the others received cognitive-guided biopsies. All procedures were realized by an experienced urologist after joint Prostate MRI analysis with urogenital radiologist.

A group of urogenital pathologists, who were blind to the MR imaging, determined the tissue core characteristics and, if present, the tumor aggressiveness according to the revised histopathological Gleason grading [17]. A Formalin-fixed, paraffin embedded, tissue block of each biopsy was analysed after Hematoxylin-Phloxin-Saffron (HPS) staining. If the diagnosis of cancer wasn't obvious on the HPS stain, immunohistochemistry was performed on an automated device (Autostainer, with Envision-plus revelation kit, Dako).

5. Statistical analysis

Analyses were conducted using SPSS software (version 19.0; IBM SPSS, Chicago, IL). The sample unit considered in this study was foci suspect for Prostate Cancer. In case of multiple lesions per prostate, there were no intra-subject clustering effects because characteristics variability of each lesion was independent from the patient himself.

Continuous variables, such as demographics and histopathological data, were given as mean ± standard deviation. Because only mpMRI-positive patients were included into analysis, negative predictive value cannot be derived from the data.

Mean PI-RADS overall score, version 1 and version 2, were compared with a Student t-test for continuous variable and paired data.

Then, cancer detection rates (positive predictive value) were determined in PI-RADS version 1 and PI-RADS version 2, according to the histopathological results, both for significant and insignificant cancer, for each of the following categories : lesions overall scored PI-RADS 5, lesions overall scored PI-RADS ≥ 4 (4 and 5) and lesions overall scored PI-RADS ≥ 3 (3, 4 and 5).

Cancer detection rates between PI-RADS version 1 and PI-RADS version 2 were compared using the McNemar test for qualitative and paired data.

A test with a p-value ≤.05 was considered to indicate a statistically significant difference.

RESULTS

1. Patient demographics, biopsy results and PI-RADS assessment (Table 1)

Ninety three patients were included in the study, with a mean age of 66.9 years (± 6.13 years), the mean pre-biopsy Prostate Specific Antigen rate was 12.6 ng/mL (± 6.37 ng/mL) and the mean cohort prostate volume, estimated by MRI, was 66.6 mL (± 39.5 mL). 143 suspicious lesions were initially described. Mean foci maximum length was 13.7mm (± 6.12 mm). 78 foci were localized in the Transition Zone, 65 in the Peripheral Zone.

According to the overall assignment of PI-RADSv1, 42 lesions were scored PI-RADSv1 overall score 5 (29%), 49 PI-RADSv1 overall score 4 (34%) and 52 PI-RADSv1 overall score 3 (36%).

Histopathological evaluation revealed 50 tumor-positive regions (34%), 15 of them being clinically significant, with a Gleason score ≥ 7=4+3 (30%), and 35 being clinically insignificant, with a Gleason score ≤ 7=3+4 (70%). Of these 50 (34%) cancer foci histopathologically identified, 29 were PI-RADSv1 overall score 5 (58%), 12 overall score 4 (24%) and 9 overall score 3 (18%). Of the 15 clinically significant cancers, 11 were previously PI-RADSv1 score 5 (73%), 2 PI-RADSv1 overall score 4 (13%) and 2 PI-RADSv1 overall score 3 (13%).

Atrophy, hyperplasia, prostatitis, fibrosis or normal tissue were diagnosed in the remaining 93 benign lesions.

According to the overall assignment of PI-RADSv2, of the 143 foci highlighted, 27 lesions were identified with a score at 5 (19%), 53 lesions with a score at 4 (37%), 31 lesions with a score at 3 (21%), 28 lesions with a score at 2 (19%) and 4 lesions were classified with a score at 1 (3%).

Among the 50 cancerous lesions, 22 were rated PI-RADSv2 overall score at 5 (44%), 23 with a score at 4 (46%), 4 with a score at 3 (8%) and 1 was rated PI-RADSv2 overall score 1 (2%). For tumors with CSD, 11 cancers obtained an overall score of 5 (73%) and 4 cancers a score of 4 (27%).

Table 1:
PI-RADS assessment and histopathologicals findings

	PI-RADS v1 overall score			PI-RADS v2 overall score				
	3 *n (%)*	**4** *n (%)*	**5** *n (%)*	**1** *n (%)*	**2** *n (%)*	**3** *n (%)*	**4** *n (%)*	**5** *n (%)*
CSD	2 (13%)	2 (13%)	11 (73%)	-	-	-	4 (27%)	11 (73%)
All cancers	9 (18%)	12 (24%)	29 (58%)	1 (2%)	-	4 (8%)	23 (46%)	22 (44%)
All lesions	52 (36%)	49 (34%)	42 (29%)	4 (3%)	28 (19%)	31 (21%)	53 (37%)	27 (19%)

CSD: Clinically Significant Disease

2. Comparison of PI-RADSv1 and v2 (Table 2)

The mean overall PI-RADSv2 score was lower than it was for PI-RADSv1 (SD=0.77; 95%CI [0.30 to 0.56] p<0.001).

The lesion-based analysis showed a cancer detection rate of 69% for foci graded PI-RADSv1 overall score 5, whereas it was 81.5% in the revised second version (p<0.001). For CSD, the detection rate was 26.2% for PI-RADSv1, 40.7% for PI-RADSv2 (p=0.03).

Concerning lesions scored PI-RADS 4 or higher, the cancer detection rate was 45% according to the PI-RADSv1, and 56.3% for the PI-RADSv2 (p=0.002). For CSD, detection rate was respectively 14.3% and 18.8% for PI-RADSv1 and v2 (p>0.05).

Finally, cancer detection rate was 35% for PI-RADS overall score ≥3 in v1 and 44.1% in v2 (p>0.05). This rate fell to 10.5% for CSD in PI-RADSv1 and 13.5% in PI-RADSv2 (p>0.05).

Table 2
Comparison of PI-RADS versions for the cancer detection rate

	PI-RADS v1	PI-RADS v2	p-value
Mean overall score	3,93±0,81	3,49±1,09	p<0.001
Cancer detection rate	**% (n)**	**% (n)**	
All lesion scored PI-RADS 5	69% (29)	81% (22)	p<0.001
CSD scored PI-RADS 5	26,2% (11)	40,7% (11)	p=0.03
All lesion scored PI-RADS ≥ 4	45% (41)	56,3% (45)	p=0.002
CSD scored PI-RADS ≥ 4	14,3% (13)	18,8% (15)	p>0.05
All lesion scored PI-RADS ≥ 3	35% (50)	44,1% (49)	p>0.05
CSD scored PI-RADS ≥ 3	10,5% (15)	13,5% (15)	p>0.05

DISCUSSION

The detection rate of prostate of prostate cancer reported in the present study, especially concerning clinically significant disease according to PI-RADSv1, was 26/%/14%/11% for PI-RADSv1 overall score of 5/≥4/≥3 respectively. Habchi et al. described a higher rate of 55%/31%/21% for similar lesions [18]. However, these authors choose a Gleason score ≥3+4 for significant disease definition, whereas a Gleason score ≥4+3, according to Epstein criteria, was used in this current study [7]. Moreover, in Habchi et al's study, the biopsy procedure was performed by the same radiologist who interpreted the mpMRI images that could improve TRUS cognitive-guided targeted biopsies precision. Roethke et al. also reported a higher detection rate, applying a clinically significant cancer definition that was

similar to this study (Gleason score ≥3+4) [19]; but, in their work, all targeted biopsies were conducted with Magnetic Resonance – TRUS three dimensional real-time fusion software, that has been proved to detect more high-grade PCa than cognitive-guided biopsy protocols [20-21].

According to the same condition of practice, other authors have reported similar results to those presented here. For example, Abd-Alazeez and al. reported a 5% detection rate for CSD with the same definition (Gleason 4+3 or higher) in PI-RADSv1 overall score ≥3 and 49% for all cancer, independent of the Gleason score [22].

As suggested by a 2014 meta-analysis, the scoring system used needed clarification because of wide variability in the interpretation and integration of the PI-RADSv1 score [9]. ESUR guidelines had to be improved in order to facilitate assessment and care, and a new revised PI-RADSv2 system attempted to answer to those expectations.

Current work highlights a statistically significant ($p<0.05$) higher rate of cancer detection in PI-RADSv2 compared to the first version of the scoring system; especially concerning lesions with PI-RADSv2 assessment 5, corresponding to a very high likelihood of CSD. Few clinical trials already published have compared both version of the PI-RADS score and revealed large heterogeneity concerning diagnostic accuracy of PCa. Kasel-Seibert et al. obtained for 39 malignant lesions a better positive predictive value in PI-RADSv2 [23]. In a retrospective work with cognitive-guided or MR fusion-guided biopsy procedures, equivalent sensitivity and specificity was found by Tewes et al. between PI-RADSv1 and v2, as in Feng et al. analysis with comparable diagnostic value, especially concerning PZ lesions [24-25]. Contrariwise, in a whole-mount step-section analysis after radical prostatectomy, Auer et al. showed a lower discriminative ability of tumor detection in v2, mostly for PZ foci. Overall scored 2 in v2 and 4 in v1, a PZ lesion corresponding to CSD (Gleason 9) was misdiagnosed because not

suspicious on DWI. For all prostate cancers, the authors found a 14% rate of false negative biopsies in PI-RADSv2, only 3% in PI-RADSv1 [26].

In this study, fewer lesions with an intermediate likelihood of PCa (PI-RADS 3) were assessed using the PI-RADSv2 scoring system; confirming one the main objectives of this revised PI-RADS version.

Most of the foci overall-scored 3 in PI-RADSv1 were downgraded in PI-RADSv2, with a low probability of PCa (assessment category 2). PI-RADSv2 does not include recommendations for management of the lesions scored 2 or 3 with low or intermediate probability of cancer; a biopsy may or may not be appropriate, depending on factors other than MRI alone, such as clinical and biological data [13].

In two cases, lesions overall-scored 3 according to PI-RADSv1 system have been re-scored 4 according to PI-RADSv2 with a high likelihood of PCa and clinical impact because in this situation biopsy was recommended. It was important to notice the performance of v2 on v1 because both were proven as CSD, with a Gleason score of 4+3 for one patient, and 4+4 for the other.

Regarding the biopsy number performed in this population under v1 recommendation, it was noticed that 44% of procedures could have been avoided following v2 without any CSD misdiagnosis. This high specificity of PI-RADSv2 scoring system for CSD was also demonstrated by Vargas et al. showing correct identification of 95% Gleason score ≥ 4+3 lesions [27].

From a clinical perspective, this comparative study validates PI-RADSv2 as a trustworthy tool for detecting CSD; all CSD found by PI-RADSv1 was scored 4 or 5 in PI-RADSv2, strengthening recommendations for biopsies of lesions assessed in PI-RADSv2 as category 4 or higher [13].

If only lesions overall-scored 4 or 5 according to PI-RADSv2 were biopsied, five non-significant cancers detected according to v1 would have been missed: four lesions scored 3 and one scored 1 in v2, all of them with Gleason score 3+3 PCa. Nevertheless, this fact has no important incidence on the diagnostic value of PI-RADSv2 because the score was designed to detect CSD.

This current study has several limitations. First, it is a single reader analysis but justified by a clinically relevant scenario, with prospective inclusion according to PI-RADSv1. Then, the selection of lesions using PI-RADSv1 could have been source of bias: foci were included according to v1 and the population would have been different if sampling was realized in accordance with PI-RADSv2 at the outset of our work. Statistical power of the study is restricted by the small number of CSD in our population.

Concerning tissue sampling, MRI/TRUS-fusion biopsies are proved to be the best procedure not to underestimate real pathology within the prostate [28-29-30]. Despite large experience of urologists, realization of cognitive-guided procedures in the wide majority of our cases (136/143) has to be considered as another limitation.

Lastly, the learning curve could have also been a contributing factor regarding the global detection rate of PCa using the PI-RADSv1 scoring system because this work started immediately after attending the ESUR course in 2013.

Larger prospective studies need to be conducted in order to definitely validate PI-RADSv2 scoring in CSD detection. This should particularly take care of inter-observer agreement, because preliminary results show as for PI-RADSv1 [31-32] a moderate agreement for detection of CSD [23-24-33]. Medium inter-observer reliability was also found by Rosenkrantz and al. but it was higher compared to v1 for Kasel-Seibert and al only for malignant lesions [23-34]. As v2 was recent, training time seems essential before clinical applicability.

Despite these comments, we consider that our methodological approach provide enough validity to demonstrate superiority of PI-RADSv2 on v1.

CONCLUSION

The present study shows the superiority of PI-RADSv2 on v1, both in detection of significant prostate cancer and in better differentiation; with an important decrease of lesions classified PI-RADS 3.

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APPENDIX

Appendix 1 :
Assignment of overall PI-RADSv2 score

Peripheral Zone			
DWI score (dominant sequence)	**DCE score (secondary sequence)**	**TWI score**	**Overall PI-RADS version 2 score**
1	Any	Any	1
2	Any	Any	2
3	-	Any	3
3	+	Any	4
4	Any	Any	4
5	Any	Any	5

Transition Zone			
T2WI score (dominant sequence)	**DWI score (secondary sequence)**	**DCE score**	**Overall PI-RADS version 2 score**
1	Any	Any	1
2	Any	Any	2
3	≤4	Any	3
3	5	Any	4
4	Any	Any	4
5	Any	Any	5

Appendix 2:

Sequences parameters of mpMRI prostate protocol

	Image plane	TR[a] (ms)	TE[b] (ms)	Fa[c] (°)	FOV[d] (mm)	Section thickness (mm)	Matrix size	*b* values (s/mm²)	Temporal resolution (sec)
1.5 T Imager (GE Excite 1.5T)									
T2-TSE[e]	Axial Coronal Sagittal	2980	131	90	200 X 200	4.0	256 X 320	N/A	N/A
DWI[f]	Axial	4400	99	90	260 X 260	4.0	94 X 94	0, 50, 400, 1000, 2000	N/A
T1 GRE[g] dynamic contrast	Axial	10.7	5	12	320 X 240	3.0	134 X 256	N/A	5.5 X 15
3.0 T Imager (Siemens Magnetom 3.0T)									
T2-TSE	Axial Coronal Sagittal	6250	113	124	180 X 180	3.0	256 X 256	N/A	N/A
DWI	Axial	5400	64	90	220 X 220	3.0	120 X 90	0, 50, 500, 1000, 2000	N/A
T1 GRE dynamic contrast	Axial	7.5	3.4	12	200 X 200	3.0	132 X 192	N/A	7.5 X 25

[a] Repetition Time, [b] Echo Time, [c] Flip Angle, [d] Field of View, [e] Turbo Spin Echo, [f] Diffusion Weighted Imaging, [g] Gradient-Echo

Appendix 3 :
PI-RADSv1 scoring system

Score	Criteria
A1. T2WI for the Peripheral Zone	
1.	Uniform high signal intensity (SI)
2.	Linear, wedge-shaped or geographic areas of lower SI, usually not well demarcated
3.	Intermediate appearances not in categories 1/2 or 4/5
4.	Discrete, homogeneous low signal focus/mass confined to the prostate
5.	Discrete, homogeneous low signal intensity focus with extracapsular extension/invasive behaviour or mass effect on the capsule (bulging), or broad (>1.5cm) contact with the surface
A2. T2WI for the Transition Zone	
1.	Heterogeneous TZ adenoma with well-defined margins : « organized chaos »
2.	Areas of more homogeneous low SI, however well marginated, originating from the TZ/ Benign Prostatic Hyperplasia
3.	Intermediate appearances not in categories 1/2 or 4/5
4.	Areas of more homogeneous low SI, ill defined : « erased charcoal sign »
5.	Same as 4, but involving anterior fibromuscular stroma or anterior horn of the PZ, usually lenticular drop shaped
B. Diffusion-Weighted Imaging	
1.	No reduction in ADC compared with normal glandular tissue. No increase in SI on any high b-value (≥b800)
2.	Diffuse, hyper SI on ≥b800 with low ADC; no focal features, however, linear, triangular or geographical features are allowed
3.	Intermediate appearances not in categories 1/2 or 4/5
4.	Focal area(s) of reduced ADC but iso-intense SI on high b-value images (≥b800)
5.	Focal area/mass of Hyper SI on the high b-value images (≥b800) with reduced ADC
C. Dynamic Contrast Enhanced MRI	
1.	Type 1 enhancement curve
2.	Type 2 enhancement curve
3.	Type 3 enhancement curve
+1	For focal enhancing lesion with curve type 2-3
+1	For asymmetric lesion or lesion at an unusual place with curve type 2-3

Appendix 4:
PI-RADS v2 scoring system

Score	Criteria
A1. T2WI for the Peripheral Zone	
1.	Uniform high signal intensity
2.	Linear, wedge-shaped or geographic areas of lower SI, usually not well demarcated
3.	Heterogeneous SI or non-circumscribed, rounded, moderate hypointensity. Includes others that do not qualify as 2, 4 or 5
4.	Circumscribed, homogeneous moderate hypointense focus/mass confined to the prostate and <1.5cm in greatest dimension
5.	Same as 4 but ≥ 1.5cm in greatest dimension or definite extra-capsular extension (ECE)/invasive behavior
A2. T2WI for the Transition Zone	
1.	Heterogeneous intermediate SI
2.	Circumscribed hypointense or heterogeneous encapsulated nodule(s) (BPH)
3.	Heterogeneous SI with obscured margins. Includes others that do not qualify as 2,4 or 5
4.	Lenticular or non-circumscribed, homogeneous, moderately hypointense, and <1.5cm in greatest dimension
5.	Same as 4, but ≥ 1.5cm in greatest dimension or definite ECE/invasive behavior
B. Diffusion-Weighted Imaging	
1.	No abnormality on ADC and high b-value DWI
2.	Indistinct hypointense on ADC
3.	Focal mildly/moderately hypointense on ADC and isointense/mildly hyperintense on high b-value DWI
4.	Focal markedly hypointense on ADC and markedly hyperintense on high b-value DWI, <1.5cm in greatest dimension
5.	Same as 4, but ≥ 1.5cm in greatest dimension or definite ECE/invasive behavior
C. Dynamic Contrast-Enhanced MRI	
–	No early enhancement OR Diffuse enhancement not corresponding to a focal finding on T2 and/or DWI OR Focal enhancement corresponding to a lesion demonstrating features of BPH on T2WI
+	Focal AND Earlier than or contemporaneously with enhancement of adjacent normal prostatic tissue

PESLERBE Sylvain

Prostate Imaging Reporting and Data System (PI-RADS) v2 contre v1 : précision améliorée pour les cancers de prostate Cliniquement Significatifs

RÉSUMÉ

Objectif :
Comparer les versions v1 et v2 du PI-RADS pour la détection des lésions de Cancer de Prostate (PCa) à l'IRM, notamment les Cancers Cliniquement Significatifs (CSD), en utilisant les résultats anatomopathologiques comme Gold-Standard.

Matériels et Méthodes :
93 patients consécutifs avec suspicion clinique ou biologique de PCa ont été inclus de Juillet 2013 à Aout 2015 et ont bénéficié d'une IRM prostatique multiparamétrique avant biopsies. Chaque lésion prostatique a été scorée prospectivement selon le score PI-RADSv1. 143 lésions suspectes de cancer ont été détectées (score global ≥ 3) et suivies de biopsies systématiques puis ciblées, soit par guidage cognitif ou par fusion d'image IRM-Echographie Transrectale. Ensuite, rétrospectivement et en aveugle des résultats anatomopathologiques, les lésions ont été de nouveau cotées selon le système PI-RADSv2. Les taux de détection ont été comparés grâce au test de McNemar, pour tous les cancers et puis uniquement ceux cliniquement significatifs.

Résultats :
Parmi les 50/143 cancers diagnostiqués (34%), 15 étaient cliniquement significatifs (30%). Le Taux de Détection de cancer était significativement plus élevé selon le PI-RADSv2 : 1) Pour les lésions avec un score global = 5 étant Cliniquement Significatives (40.7% contre 26.2%, p<0.001) et tous les cancers (81.5% contre 69.0%, p=0.03) 2) Pour tous les Cancers ayant un score global ≥ 4 (56.3% contre 45.1%, p=0.002).

Conclusion :
Cette étude démontre la supériorité du système PI-RADSv2 sur v1, à la fois pour la détection des cancers de prostate cliniquement significatifs, ainsi qu'une meilleure caractérisation lésionnelle avec une baisse importante du nombre de lésions indéterminées PI-RADS = 3.

Mots-clés : Cancer de la Prostate ; PI-RADS ; IRM ; Etude Comparative ; Urologie

Updated Prostate Imaging Reporting and Data System (PI-RADS) v2 versus v1: improved detection accuracy in Clinically Significant Prostate Cancer

ABSTRACT

Objective:
To compare the new revised PI-RADSv2 to v1 for detection of Prostate Cancer (PCa) lesions focused on Clinically Significant Disease (CSD), using histopathology as the reference-standard.

Materials and Methods:
From July 2013 to August 2015, 93 consecutive patients with clinical or biological PCa suspicion were included and underwent Multi-parametric MRI before biopsy. Foci were assessed and prospectively scored according to the PI-RADSv1. 143 suspicious lesions were detected, (overall score ≥ 3), and imaging fusion-guided or cognitive-guided biopsies were performed. Then, blinded from histopathological outcomes, lesions were rescored retrospectively, using PI-RADSv2. All cancer and CSD (Gleason score ≥4+3 or maximal core length ≥ 4mm) detection rates were compared by the McNemar test.

Results:
Of the 50/143 cancers diagnosed (34%), 15 were clinically significant (30%). Cancer detection rate was significantly higher with PI-RADSv2: 1) for PI-RADS overall score = 5 both in CSD (40.7% versus 26.2%, p<0.001) and All Cancers (81.5% versus 69.0%, p=0.03) and 2) for PI-RADS overall score ≥ 4 in All Cancers (56.3% versus 45.1%, p=0.002).

Conclusion:
The present study shows the superiority of PI-RADSv2 on v1, both in detection of significant Prostate Cancer and in better differentiation with an important decrease of lesions classified PI-RADS 3.

Keywords : Prostate Cancer ; PI-RADS ; MRI ; Comparative Study ; Urology

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