Updated Prostate Imaging Reporting and Data System (PI-RADS) 2.0 versus 1.0: detection accuracy of prostate clinically significant and insignificant cancer

Poster No.: C-1203
Congress: ECR 2016
Type: Scientific Exhibit
Authors: S. PESLERBE¹, C. Nedelcu¹, P. BAZERIES¹, M. KULIK², C. Ridereau-Zins¹, C. Aubé¹, Angers/FR, Saint Barthelemy d'Anjou/FR
Keywords: Genital / Reproductive system male, Oncology, MR, Comparative studies, Neoplasia
DOI: 10.1594/ecr2016/C-1203

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Aims and objectives

Background

Prostate cancer (PCa) is the most common malignancy in men in Western countries and its incidence is expected to double by 2030 [1]. Multiparametric Magnetic Resonance Imaging (mp-MRI) has become an increasingly common adjunctive procedure in PCa detection with both morphological T2-weighted (T2w) and functional diffusion (DWI) and dynamic contrast enhancement (DCE) sequences [2-3].

Prostate Imaging Reporting and Data System (PI-RADS)

To bring standardization in reporting of prostate mp-MRI in the detection of clinically significant cancer, the European Society Urogenital Radiology (ESUR) published a unified PI-RADS in 2012 [4]. Several studies have validated the scoring system [5], but radiologists experience and new publications suggested that different weighting should be used depending on the localisation of the lesion in the peripheral zone (PZ) or transitional zone (TZ) and showed that DCE sequences should be less essential [6-7]. Therefore, the original PI-RADS was revised as a second version, PI-RADS version 2.0 and published in 2014 [8].

Purpose

To compare the new revised PI-RADS version 2 with the first version, in diagnostic accuracy for detection and characterisation of clinically significant or insignificant cancer lesions, correlated with histopathological gold-standard results.

Methods and materials

Patients and Study design

This prospectively design and single institutional study was conducted with the accordance of the local ethics committee. The population sample concern 93 consecutive patients with clinical or biological PCa suspicion, included 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 in the study if they showed at least one suspicious lesion, defined by a PI-RADS overall score # 3.

First, each lesion was classified according to the first version of PI-RADS, before the further biopsy procedure. In a second time, blinded for histopathologics results, all the lesions were scored in accordance with the revised PI-RADS version 2. Correlation of pathologic results with each of the both version of PI-RADS for PCa detection performance were then statistically compared.

**Multiparametric MRI protocole**

From July 2013 to October 2014, MR examinations were performed by using 1.5T system (GE Excite 1.5T, GE Healthcare, Milwaukee, WI, USA), then until August 2015, patients underwent MR prostate imaging by a 3.0T imager (Siemens Magnetom 3.0T, Siemens Healthcare, Erlangen, Germany).

The imaging protocol was in accordance with the ESUR guidelines with both morphological and functional MR imaging techniques. Technical parameters are resumed in Table 1 on page 4.

**Image Interpretation and PI-RADS assessment**

Images of all patients were read by a radiologist with eight years of experience in prostate MR imaging interpretation, including one year working with the first PI-RADS assessment system, after participation in international training sessions.

Every lesion was assigned a score from 1 to 5 for each sequence (T2/DWI/DCE) and was documented on a 27-sector scheme. Instead of an overall sum score, we appraised semiquantitatively each lesion according to the ESUR PI-RADS version 1 Likert-like global score (Table 2 on page 5). Prostatic volume and maximum foci length were also compiled.

In a second time we retrospectively reviewed our database of PI-RADSv1 lesions and, blinded from the histopathologic outcomes scored it again, according to the revised PI-RADS version 2 (Table 3 on page 6 and Table 4 on page 6).

**Biopsy protocol and Pathological analysis**
Only lesions with PI-RADSv1 # 3 were biopsied. Patients were referred to an urologist within our establishment. Each patient underwent both standard 12-core transrectal US-guided sextant biopsies, plus 3 to 6 targeted-biopsies according to MRI reporting and delivered schema. For 5 patients, MR/TRUS fusion platform was used (BIOJET FUSION system and software, D&K Technologies, Barum, Germany), others received cognitive guided biopsies.

A fellowship-trained urogenital pathologist, blinded from MR imaging, determined the tissue core characteristics and, if present, tumour aggressiveness according to the revised histopathological Gleason grading [9]. 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 HPS stain, immunohistochemistry was performed on an automated device (Autostainer, with Envision-plus revelation kit, Dako).

**Statistical analysis**

Analyses were done using SPSS software (version 19.0; IBM SPSS, Chicago, IL). Continuous variables as demographics and histopathologic data were given as mean ± standard derivation.

Mean PI-RADS overall score version 1.0 and version 2.0 were compared with Student t-test for continuous variable and paired data.

Then, cancer detection rates were determined in PI-RADSv1 and v2, according to anatomopathologic results, both for significant and insignificant cancer, for each 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 PIRADS version 2 were compared by using the McNemar test.

A test with a P-value # 0.05 was considered to indicate a statistically significant difference.

**Images for this section:**
Table 1: Sequences parameters of mp-MRI prostate protocol

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Table 2 PI-RADS version 1.0 scoring system

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 extra capsular 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: “organised 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 the anterior fibromuscular stroma or the anterior horn of the PZ, usually lenticular or water-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 image (2b800)
2. Diffuse, hyper SI on 2b800 image 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 (2b800)
5. Focal area/mass of hyper SI on the high b-value images (2b800) 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

Overall PI-RADS 1.0 Likert-like global score
Score 1 = Clinically significant disease in highly unlikely to be present
Score 2 = Clinically significant cancer is unlikely to be present
Score 3 = Clinically significant cancer is equivocal
Score 4 = Clinically significant cancer is likely to be present
Score 5 = Clinically significant cancer is highly likely to be present
Table 2: PI-RADS version 1.0 scoring system

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Table 3: PIRADS version 2.0 scoring system

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Table 4: Assignment of overall PI-RADS version 2.0 score

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<th>DCE score (secondary sequence)</th>
<th>T2WI score</th>
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Table 4: Assignment of overall PI-RADS version 2.0 score

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Results

**Patients demographics, biopsy results and PI-RADS assessment**

The mean age of the population sample was 66.9 years (±6.13 years), the mean prebiopsy PSA rate was 12.6 ng/mL (± 16.3 ng/mL) and the mean cohort prostate volume estimated by MRI was 66.6 cc (± 39.5 cc).

143 suspicious lesions were initially described according to PI-RADS V1. Mean foci maximum length was 13.7 mm (± 6.12 mm). 71 foci were localized in transition zone, 72 in peripheral zone.

42 lesions were scored according to PI-RADS V1 overall score 5 (29%), 49 PI-RADS V1 overall score 4 (34%) and 52 PI-RADS V1 overall score 3 (36%).

Histopathologic evaluation revealed 50 tumor-positive regions (35%) including 15 clinically significant with a Gleason score # 7 = 4+3 (30%) and 35 clinically insignificant with a Gleason score # 7 = 3+4 (70%).

Of the 50 (35%) cancer foci histopathologically identified, 29 were PI-RADS overall scored 5, 12 overall scored 4 and 9 overall scored 3. (Table 5 on page 9). Of the 15 clinically significant cancer, 11 were previously scored 5, 2 PI-RADS overall score 4 and 2 PI-RADS overall score 3 (13%). (Table 6 on page 10). Atrophy, hyperplasia, prostatitis, fibrosis or normal tissue were diagnosed in the remaining 93 benign lesion.

According to PI-RADS 2.0, retrospective reviewing of the 143 foci highlighted 27 lesions with a score at 5 (19%), 53 lesions with a score at 4 (37%), 31 lesions with a score at 3 (21%), 28 lesion with a score at 2 (19%) and 4 lesions classified with a score at 1 (3%).

Among the 50 cancerous lesions, 22 were rated PI-RADS overall score at 5 (44%), 23 with a score at 4, 3 with a score at 3 and 1 was rated PI-RADS version 2 overall score 1 (2%). (Table 5 on page 9).

For clinically significant disease, 11 cancers obtained an overall score of 5 and 4 cancers a score of 4. (Table 6 on page 10).

**Statistical Results**
Mean overall PI-RADS version 2.0 score was significantly lower than it was for PI-RADS version 1.0.

The lesion-based analysis showed a significant higher cancer detection rate of 69% for foci graded PI-RADS version 1.0 overall score 5, whereas it was 81.5% in the revised 2.0 version (p<0.001). For clinical significant disease (CSD) detection rate was 26.2% for PI-RADS 1.0 and 40.7% for PI-RADS 2.0 (p=0.03).

Concerning lesions scored PI-RADS 4 or higher, cancer detection rate was 45% according to the PI-RADS version 1 and 56.3% for the PI-RADS version 2 (p=0.002). For CSD, detection rate was 14.3% and 18.8% for PI-RADS version 1 and version 2 respectively. (p>0.05).

Finally, cancer detection rate was 35% for PI-RADS overall score # 3 in the first version, 44.1% in the revised one (p>0.05). The detection rate was only 10.5% for clinically significant disease in PI-RADS 1.0, and 13.5% in PI-RADS 2.0 (p>0.05).

Results are resumed in Table 7 on page 10.

Images for this section:

Table 5: PI-RADS version 1 and version 2 assessment for all cancers histopathologicaly prooven
Table 6: PI-RADS version 1 and version 2 assessment for Clinically Significant Disease (CSD)
Table 7: Comparison of cancer detection rate in PI-RADS version 1 and version 2

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Conclusion

In our study PI-RADS version 2 showed significant better detection rate compared to PI-RADS version 1 for CDS.

For overall cancers the detection rate of PI-RADS V2 is proved to be significantly better for very high risk lesions (PI-RADS 5)

Lesions scored PI-RADS 3 in both versions determined an important decrease of the detection rate.

PI-RADS version 2 found all the CDS; only one non significant cancer was missed by PI-RADS Version 2 (scored 1)

Our study limitation is the lack of statistical strength, mainly related to the small number of CSD in our population sample.

Personal information

References


