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Systematic biopsy is unnecessary for the detection of clinically significant prostate cancer in men with PIRADS 5 and PSA density greater than 15%

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Introduction: To evaluate the detection of clinically significant prostate cancer (CSPCa) by systematic (SB) and target biopsy (TB) in men with Prostate Imaging Reporting and Data System - PIRADS 5; and the need for SB in this population.

Materials and methods: We identified consecutive patients with PIRADS 5 lesion on multiparametric MRI (mpMRI; 3 T, T2W, DWI, ADC, DCE) undergoing prostate biopsy (PBx) for suspicion of PCa, from our PBx database (IRB# HS-13-00663). Patients underwent mpMRI followed by 12-core SB and at least two TB cores per PIRADS 5 lesion. All MRIs were re-reviewed by an experienced radiologist. PBx were performed by an expert urologist using an MRI-transrectal ultrasound fusion system (Koelis). Each core-biopsy was labeled individually and interpreted according to ISUP Grade Group (GG) standards. Men with prior treatment for PCa or poor-quality MRI were excluded. The positive predictive value (PPV) of PIRADS 5 on MRI for CSPCa (GG ≥ 2) detection on PBx was analyzed. PSA density (PSAD) was calculated by dividing PSA by prostate volume on MRI.

Results: A total of 124 patients met inclusion criteria. The median (IQR) age, PSAD, number of positive cores, cancer core length and percent were: 69Y (64–75), 0.23 ng/ml/cc (0.13–0.36), 7 (5–9), 12 mm (9–15) and 90% (70–95), respectively. The CSPCa detection rate for SB+TB, TB and SB was 88%, 82% and 65%, respectively. SB added 6% CSPCa detection to TB. The PPV for SB + TB of PIRADS 5 for any GG PCa and for CSPCa was 95% and 88%. Only 6 (6/124 = 5%) patients were not diagnosed with PCa on PBx: 2 with granuloma, 2 HGPIN, 1 focal inflammation, 1 benign prostatic tissue, but with metastatic PCa on pelvic lymph node biopsy. Considering only patients with PSAD > 0.15 ng/ml/cc (N = 86; 68% of the entire cohort), the CSPCa detection rate for SB+TB, TB and SB was: 95%, 92% and 72%. SB added 3% CSPCa detection to TB. Three (3/86 = 3.5%) patients with PSAD > 0.15 ng/ml/cc were diagnosed with CSPCa only on SB, and GG 1 PCa on TB. Had they been diagnosed with GG 1 on TB alone; these patients would not meet criteria for active surveillance because of high PSA or large cancer volume. The PPV for SB + TB of PIRADS 5 for any GG PCa and for CSPCa in men with PSAD > 0.15 ng/ml/cc was 98% and 95%, respectively.

Conclusions: PIRADS 5 on mpMRI showed high positive predictive value for CSPCa on prostate biopsy. In those with PSAD > 0.15 ng/ml/cc, systematic biopsy marginally increased CSPCa, but not overall PCa detection in comparison to target biopsy alone. Systematic biopsy didn't affect patients' management and could be omitted on this population.

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Upstaging after radical prostatectomy in clinically localized intermediate and high-risk prostate cancer: The role of obesity

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Introduction: To evaluate body mass index (BMI) as risk factor for lymph node invasion (LNI) in patients with clinically localized intermediate- and high-risk classes prostate cancer (PCa) according to European Association of Urology (EAU) risk classification.

Materials and methods: Patients with clinical intermediate and high EAU risk classes without LNI underwent RP with or without ePLND. The decision to perform an extended lymph node dissection in intermediate risk class patients was based on pre-operative nomograms showing a risk of lymph node invasion greater than 5%. Clinical parameters as BMI, total testosterone (TT), percent of positive cores (BPC) and others were evaluated. Patients were stratified according to EAU classes, BMI and BPC. Multinomial logistic regression was used to evaluate the association of clinical factors with the risk of multiple occult metastases.

Results: Between November 2014 and December 2018, 726 consecutive Caucasian patients were enrolled. Among these, robot-assisted radical prostatectomy (RARP) was performed in 640 cases (88.2%) and open retro-pubic radical prostatectomy (ORP) in 86 subjects (11.8%). The distribution of the patient population according to EAU risk classes was as follows: low risk 176 cases (24.2%), intermediate risk 386 subjects (53.2%), high risk 118 patients (16.3%) and locally advanced 46 cases (6.3%). Extended PLND was performed during 446 RARPs (69.7%) and 79 ORPs (91.9%). Clinically localized PCa was diagnosed in 404 patients of which 343 (84.9%) underwent RARP and 61 (15.1%) underwent RRP. The LNI rate was higher in the EAU high-risk class (23.7%) compared to the EAU intermediate risk class (9.1%). The distribution of multiple occult metastases was higher in the EAU high-risk class (11.9%) compared to the intermediate class (3.5%). BMI, BPC and EAU risk group were significantly associated with the risk of LNI. Significantly lower TT levels were detected in overweight and obese patients compared to cases with BMI < 25 kg/m².

On multivariate analysis, obesity was an independent predictor of multiple LNI (OR = 3.219; 95%CI: 1.186–8.734), together with BPC > 50% (OR = 3.281; 95%CI: 1.323–8.138) and EAU high-risk class (OR = 3.080; 95%CI: 1.275–7.440).

Among metastatic patients, being overweight (OR = 4.533; 95%CI: 1.212–16.963) and obesity (OR = 5.950; 95%CI: 1.223–28.951) were the only clinical factors associated with the risk of multiple lymph node metastases.

Conclusions: BMI is an independent predictor of the risk of multiple lymph node metastases in patients with clinically localized intermediate- and high-risk EAU classes PCa staged by an ePLND template. In EAU intermediate and high-risk classes, obese patients represent a special risk category harboring clinically occult multiple metastases. BMI should be considered in the LNI risk calculators.

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Radiomic analysis of T2 and ADC mpMRI images in the diagnosis of clinical significant prostate cancer: An early experience

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Introduction: PI-RADS score V2 assesses the likelihood of clinically significant (CS) Prostate Cancer (PCA) at multiparametric (mp) magnetic resonance imaging (MRI). PI-RADS score improved the detection of CS PCA but still have some limitations. It is operator dependent, doesn't give informations about tumor aggressiveness and was not designed for 3D volume delineation. Radiomic is an artificial intelligence (AI) technique considered as an emerging approach for imaging evaluation. It's able to extract quantitative data from images and to build mathematic models for the prediction of PCA learning more and more from data acquisition. Aim of our study was to develop a Radiomic tool analysis by using T2 weighted (T2w) and apparent diffusion coefficient (ADC) MRI imaging addressing its diagnostic accuracy, sensitivity and specificity for the diagnosis of CS PCA.

Materials and methods: From September 2018 to August 2019, 91 patients underwent MRI systematic plus targeted fusion biopsy at our Institution. MRI images (T2 and ADC) of all the prostate gland

including target lesions were used for radiomic analysis. Region of interest (ROI) was defined as prostate volume. In 91 patients, ROI were evaluated and from these 91 ROI, 484 image features using radiomic analysis were extracted. Prostate cancer aggressiveness was assessed by combining Three Orthogonal Planes-Local Binary Pattern (TOP-LBP), Gray Level co-occurrence Matrix 3D (GLCM 3D) and other first order statistical features with clinical (semantic) features (Digital Rectal Examination of prostate, PSA, highest PI-RADS). The 487 features were used to teach the computer to independently predict the Gleason Score (GS). In order to select the most predictive features, we used a feature selection algorithm. At the end of the process, 9 features were chosen and used to predict if GS was ≥ 7 at final pathology through a 10 fold cross validation with a Random Forrest Classifier. True Positive was considered the number of CS correctly predicted by the computer. True Negative was considered the number of Non CS correctly predicted by the computer.

Results: The feature analysis revealed a detection accuracy of 83.5%, with a CS precision of 84.4% and a CS sensitivity of 91.5%. The resulting AUC was 80.4%. Radiomic analysis of MRI images of patients undergoing targeted fusion biopsy allowed us to develop a tool able to predict Gleason Score ≥ 7 .

Conclusions: This new tool may improve the detection rate of CS PCA and overcome the limit of subjective interpretation of MRI images reducing the number of useless biopsies.

SC39 Real time High-Resolution Micro-Ultrasound guided biopsy: A new strategy to overcome systematic prostate biopsy

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Introduction: MpMRI has been shown to improve the detection of clinically significant PCa (csPCa), yet the consistent number of csPCa missed at MRI-target biopsy prevents us from omitting systematic biopsies (SBx). Micro-Ultrasound (mUS) has emerged as a new imaging modality providing real-time stratification of prostate tissue according to the PRI- MUS protocol, that has been developed to standardize the likelihood of PCa risk. We evaluated the reliability of mUS in identifying Pca-free regions, potentially avoiding the SBx of such areas without decreasing csPCa detection.

Materials and methods: We prospectively collected data on 199 patients imaged with the ExactVu mUS system at our center from February 2019 to January 2019. All patients were scheduled for prostate biopsy due to clinical suspicion of PCa (abnormal DRE or elevated PSA). Prostate was systematically divided in 12 regions. The PRIMUS (1–5 score) protocol was used to stratify for likelihood of PCa risk. At least one biopsy core was obtained for each area and all lesions identified and classified as PRIMUS score ≥ 3 were targeted. The presence of overall PCa and csPCa (defined as GS ≥ 7 PCa) was determined. The diagnostic accuracy of mUS was determined.

Results: Median patient age was 63.9 (IQR 57–69) yr. Median total PSA was 8,6 (IQR 5.1–9.6) ng/mL and median prostate volume was 57 (IQR 35–72) mL. 51 (25.6%) patients had positive DRE. 81 (40.7%) patients were in the repeat biopsy setting. Overall PCa and csPCa detection rates were 56.8% (n = 113) and 41.2% (n = 82), respectively. A PRIMUS 1 score was assigned to 391 (16.4%) regions: 370 (94.6%) were negative for PCa and 9 (2.3%) positive for csPCa. Hence, PRIMUS 1 score provided a negative predictive value for csPCA of 97.7%. A PRIMUS 2 score was

assigned to 968 (40.5%) areas: 853 (88.1%) were negative for PCa and 61 (6.3%) were positive for csPCa. In 80/82 csPCa patients the core with the highest GS was located in a PRIMUS ≥ 3 area. 5 patients diagnosed with GS6 Pca were identified on random biopsy alone, while having only PRI-MUS 1–2 regions on mUS. Overall, we could virtually avoid the biopsy of 1359 out of 2388 (56.9%) prostate regions missing only 2 (2.4%) csPCa diagnoses while reducing the diagnoses of non-csPCa.

Conclusions: According to our preliminary results, mUS could represent a valid tool to overcome the systematic randomized biopsy of the whole prostate. Given its high accuracy in identifying cancer-free regions, it could be used to provide a real-time targeting of any suspicious area, while avoiding the SBx when mUS is negative.

SC40 Clinical and radiological characteristics affecting clinically significant prostate cancer detection in PI-RADS- v2 Score 3 index lesions

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Introduction: The aim of our study was to evaluate the impact of clinical and radiological characteristics in the detection of clinically significant prostate cancer (csPCa) in patients with a single PIRADS v2 score 3 index lesion at multiparametric MRI (mpMRI), submitted to MRI/TRUS fusion targeted biopsy (TB).

Materials and methods: Between January 2015 and March 2020, we submitted to TB patients with clinical suspicion of PCa and a PIRADS v2 score 3 single index lesion at mpMRI (1.5 T magnet with endorectal coil). Patients were then stratified in two groups: those resulted negative or ISUP grade 1 PCa (Group 1) at pathological examination and those with a diagnosis of csPCa (ISUP grade ≥ 2 ; Group 2). In group 1 and 2 we evaluated clinical and radiological characteristics and performed univariate analysis to predict factors affecting the csPCa diagnosis. Multivariate analysis predicting features influencing overall survival was also carried on.

Results: Overall, 389 patients underwent TB with a PIRADS v2 score 3 index lesion at mpMRI. TB resulted negative or positive for ISUP grade 1 PCa in 280 cases (Group 1) and positive for csPCa in 109 cases (Group 2). Table 1 compares clinical and radiological characteristics between the two groups. PSA and PSA density were significantly higher in group 2 (9 ± 6.5 ng/mL and 0.2 ± 0.1 ng/mL/cc vs 7 ± 3.8 and 0.13 ± 0.08 , respectively; both $p < 0.001$). Familiarity for PCa was present in 34.8% of group 2 patients vs 12.1% of those in Group 1 ($p < 0.001$). MRI performed at our center resulted significantly more numerous in Group 2 (92.7% vs 47.9%; $p < 0.001$). Table 2 shows pathological characteristics and complications in the two groups, with no differences in bleeding, sepsis and hospitalization rates. Table 3 displays univariate analysis of factors affecting csPCa diagnosis and multivariate analysis of parameters influencing overall survival. Positive digital rectal examination (DRE), PSA level > 4 ng/mL, PSA density and mpMRI performed at our center resulted significantly related to csPCa finding ($p < 0.001$) at univariate analysis and to a reduced overall survival at multivariate analysis ($p < 0.001$).

Conclusions: In PIRADS v2 score 3 index lesions, PSA level, PSA density, positive DRE and familiarity for PCa are factors that increase the chance to diagnose csPCa at TB. No less important is the need for mpMRI to be performed in a high volume referral center with trained and specific uro-radiologists.