

positive (40%), while 3 were positive at FB only (4%) and 29 at RB only (33%). Stratifying by PIRADS score, overall PCa detection was 57% in PIRADS 3, 81% in PIRADS 4 and 89% in PIRADS 5. As far as CSPCa, 37 CSPCa were diagnosed (43%). Specifically, 12 CSPCa were correctly identified by FB only, 14 with both methods, and 11 with RB only. Therefore FB alone would have missed 11/37 CSPCa (30%), of which 2/37 would have been diagnosed as NCSPCa and 9/37 would have been undiagnosed. Otherwise SB alone would have missed 12/37 CSPCa (32%), of which 11/37 would have been diagnosed as NCSPCa and 1/37 would have been undiagnosed. Stratifying by PIRADS score, CSPCa detection was 24% in PIRADS 3, 48% in PIRADS 4 and 50% in PIRADS 5. Finally, Gleason score did not show a good concordance between FB and RB, with a k value of 0.435.

Discussion: mpMRI with FB provide an added diagnostic value to RB in the detection of any and CSPCa in men under AS for PCa undergoing repeated biopsy. The present data support the adoption of FB in conjunction with RB in this setting of patients.

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Magnetic Resonance Imaging alone should not be considered as a stand-alone test for disease reclassification of men in Active Surveillance

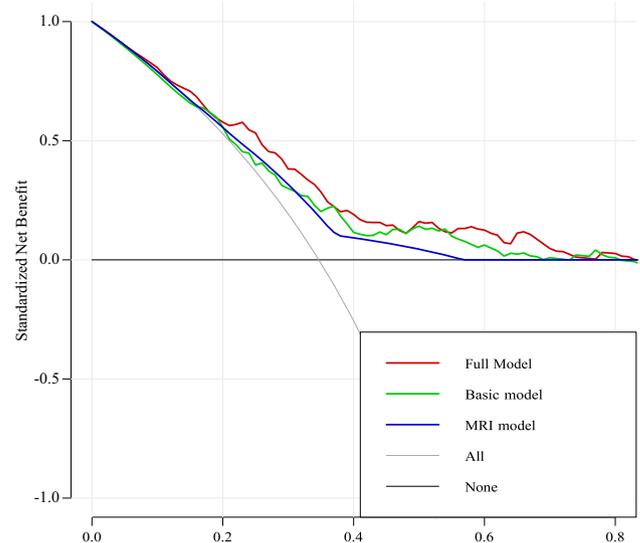
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Aim of the study: The aim of the study is to evaluate whether mpMRI alone could be used as a stand-alone test suggesting risk of reclassification in men in AS.

Materials and methods: We retrospectively evaluated 399 pts undergoing confirmatory or follow-up biopsy according to PRIAS protocol, from January 2016 to March 2019. All patients were submitted to mpMRI on a 1.5 T or 3T magnet, using triplanar high-resolution T2-w, axial DWI, and 3D T1-w dynamic contrast-enhanced sequences after injection of paramagnetic contrast agent. Pts with negative (-) mpMRI subsequently underwent systematic random biopsy. Pts with positive (+) mpMRI (PI-RADS-V2 score 3) underwent targeted fusion prostate biopsies (3 cores) + systematic random biopsies (12–18 cores). Multivariate logistic regression analyses (MVA) was used to create three model predicting the probability of disease reclassification (defined as presence of PCa $GS \geq 3+4$ at prostate biopsy): a basic model including only clinical variables (age, PSAD and number of positive cores at baseline); a MRI model including only PI-RADS score; a full model including both the previous ones. The predictive accuracy (PA) of each model was quantified using the AUC. The clinical net benefit deriving from the use of each model was assessed with the use of decision curve analysis.

Results: Median patient age and PSA was 67 yrs and 6.3 ng/ml, respectively. Median PSA density was 0.12 ng/ml/cm³. Median number of positive cores at initial biopsy was 1 (IQR:1,2). One-hundred five pts (27.3%) had mpMRI(-); 80 pts (20.0%), 168 (42.1%), and 46 (11.5%) had PI-RADS 3,4, and 5 lesions, respectively. At a median follow up of 12 months, 124 patients (31.1%) were reclassified and switched to active treatment. In pts with mpMRI(-) the rate of reclassification was 21%. In mpMRI(+), the overall rate of reclassification, at target + random biopsies, was 31%, 34% and 53% according to PI-RADS 3, 4 and 5, respectively. In the basic model, PSAD and the number of positive cores at baseline biopsy were independent predictors of risk of reclassification ($p = 0.001$; OR 12.4 and $p < 0.001$; OR 2.4, respectively), with a PA of 68%. In the MRI model, PI-RADS 4 and PI-RADS 5 were predictor of reclassification ($p = 0.038$; OR 2.45 and $p = 0.002$; OR 4.76, respectively) and the PA was lower than in the basic model (AUC 64%). The full model, that includes clinical variables and MRI results, had the best PA of 73%. PSAD ($p = 0.01$; OR 22.6), number of positive cores at baseline ($p < 0.001$; OR 1.70), and PI-RADS

4 and PI-RADS 5 ($p = 0.033$; OR 2.83 and $p = 0.021$; OR 3.76, respectively) were independent predictors of reclassification. Figure 1 depicts clinical net benefit deriving from the use of the three evaluated models.



Discussion: MRI alone should not be used in clinical practice as a stand-alone trigger for disease reclassification. The combination of MRI and other clinical variables still represents the most accurate approach to patients on AS.

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Role of the prostatic multiparametric magnetic resonance in the patient with prostatic neoplasia in active surveillance

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Aim of the study: The study has the purpose of defining and evaluate the role of the multiparametric magnetic resonance (mpMR) inside the protocol of active surveillance of low risk prostatic neoplasia. More specifically, the results of the mpMR have been evaluated between the first random biopsy set, that pointed out the presence of low risk prostatic neoplasia, and the first confirmation biopsy. The bioptic upgrade rate has been evaluated on the mpMR findings related to the PI-RADS score assigned. In this way the radiological performances have been assessed to consolidate their use in the mentioned diagnostic timing.

Materials and methods: The study is retrospective and it evaluates the records of 123 patients who have undergone the mpMR in the period between January 2016 and June 2018, during the protocol of AS in accordance with the EAU criteria: (Gleason Score 6, N° of positive core <3 with less than 50% neoplastic involvement per core, stage T1c or T2a, PSA < 10 ng/ml, PSA density < 0.15). A further selection has been carried on related to the timing of the in-depths mpMR had to be after the first random biopsy set (within 6 months) and before the confirmation biopsy (within 6 months, fusion or cognitive). In this way the study cohort has been reduced to 47 patients. The mpMR findings have been classified following the PI-RADS criteria and divided into two groups: PI-RADS ≤ 3 and PI-RADS ≥ 4 . The biopsy results that identified an upgrade have been evaluated through the application of two interpretation model, EAU and PRIAS, in order to determine the possible exit from the AS protocol. Bioptic upgrade criteria: EAU: $GS > 6$ (3 + 3) and/or $GS = 6$ (3 + 3) with >2 positive core; PRIAS: $GS > 6$ (3 + 3). Confirmation of low risk neoplasia: EAU: $GS < = 6$

(3 + 3) and/or ≤ 2 positive core; PRIAS: GS ≤ 6 (3 + 3). The correlation between bioptic Gleason Score and PI-RADS has been verified with Chi-square test and the elaboration of the ROC curve.

Results: In our study we had 16 patients PI-RADS ≤ 3 and 31 patients PI-RADS ≥ 4 . According to EAU criteria our biopsy findings were a confirmation of the diagnosis in 20 patients, whereas 27 reported an upgrade. The results are statistically significant ($p = 0,004$). Up to 77,4% of the PI-RADS ≥ 4 showed a bioptic upgrade, in contrast with only 18,8% of the PI-RADS ≤ 3 . The ROC curve analysis on the bioptic upgrade findings related to the PI-RADS score, confirmed the cut off ≥ 4 as the indicator for bioptic upgrade, with a sensibility of 88,9% and specificity of 65%. Bioptic findings using PRIAS classification showed a confirmation of the diagnosis in 29 patients and an upgrade in 18. Up to 54,8% of the PI-RADS ≥ 4 showed an upgrade, compared with only 6,2% of the PI-RADS ≤ 3 . With the application of PRIAS criteria, ROC curve analysis demonstrates a greater sensibility (94,4%) in the bioptic upgrade identification when PI-RADS ≥ 4 .

Discussion: Our study highlights the importance of the mpMR in guiding the targeted biopsies and clinical decision process in this setting of patients.

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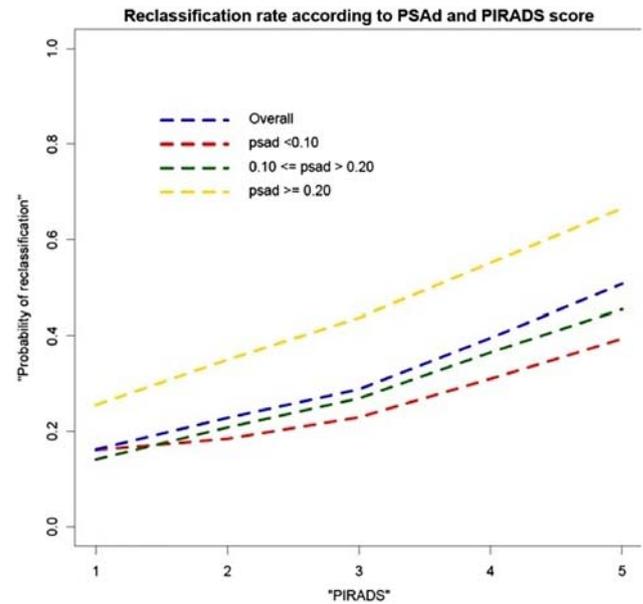
Magnetic Resonance Imaging and Ultrasound Fusion Biopsy in follow-up of patients in Active Surveillance protocol. Can PSA density discriminate patients at higher risk of reclassification?

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Aim of the study: Multiparametric (mp)MRI is increasingly used in the management of patients in Active Surveillance (AS). The aim of the study is to evaluate the rate of reclassification in men in AS, stratified on the basis of PI-RADS lesions and PSA-density (PSAD).

Materials and methods: From 01/2016 to 03/2019 399 pts underwent mpMRI before confirmatory/follow-up biopsy according to PRIAS protocol. Pts with negative (-) mpMRI subsequently underwent systematic random biopsy. Pts with positive (+) mpMRI (PI-RADS-V2 score ≥ 3) underwent targeted fusion prostate biopsies (3 cores) + systematic random biopsies (12–18 cores). The primary objective of the study was the rate of reclassification, defined as the presence of clinically significant (cs)PCa with Gleason score $\geq 3 + 4$. Different PSAD cut-off values were tested (<0.10 ; $0.10-0.20$; ≥ 0.20). Multivariable logistic regression analyses (MVA) were used to predict the risk of overall reclassification during follow-up according to PSAD, after adjusting for covariates.

Results: Median patient age, PSA and PSAD were 67 yrs, 6.3 ng/ml, and 0.12 ng/ml/cm³. Median number of positive cores at initial biopsy was 1 (IQR:1,2). One-hundred five pts (27.3%) had mpMRI(-); 80 pts (20.0%), 168 (42.1%), and 46 (11.5%) had PI-RADS 3,4, and 5 lesions, respectively. At a median follow up of 12 months, 124 patients (31.1%) were reclassified. In pts with mpMRI(-) the rate of reclassification was 21%, while was 31%, 34% and 53% according to PI-RADS 3, 4 and 5, respectively. When we stratified to PSAD, in case of PSAD <0.10 the rate of reclassification was 16%, 22%, 31%, 40% for mpMRI(-),PI-RADS 3, 4 and 5, respectively. In case of PSAD ≥ 0.20 the rate of reclassification was 25%, 35%, 55%, 67% for mpMRI(-),PI-RADS 3, 4 and 5, respectively (Fig.1). At MVA, PSAD ≥ 0.20 ($p = 0.036$; OR 1.9), PI-RADS 4 ($p = 0.030$; OR: 2.0) and PI-RADS 5 ($p < 0.001$; OR 4.8) were associated with the higher risk of reclassification, together with the number of positive cores at baseline ($p = 0.001$; OR 1.4).



Discussion: PSAD ≥ 0.20 may improve predictive accuracy of mpMRI results for reclassification of low-risk PCa pts in AS. PSAD <0.10 may help selection of pts at lower risk of harboring csPCa, in the PI-RADS 3,4 and 5 groups. However, it should be highlighted that the risk of reclassification is not negligible at any PSAD cut-off value, also in case of mpMRI(-).

SC45

Diagnostic performance of micro-ultrasound in a contemporary cohort of patients in active surveillance for localized prostate cancer: A single-institutional experience

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Aim of the study: Active surveillance (AS) represents an important alternative to active treatment strategies in patients diagnosed with low-risk prostate cancer (PCa). However, proper selection of AS candidates represents one of the most challenging tasks for urologists. Multiparametric MRI has recently been proposed as an effective diagnostic tool to properly select patients for AS, but its large-scale adoption is still limited by cost-effectiveness considerations. Micro-ultrasound (microUS) is a new imaging modality with a spatial resolution down to 70 μ m. We explore the diagnostic effectiveness of microUS within a contemporary cohort of AS patients.

Materials and methods: Data on 68 patients who were previously enrolled in the PRIAS protocol and subsequently imaged with the ExactVu micro-US system between October 2017 and April 2019 were prospectively collected. All patients were scheduled for a confirmatory prostatic biopsy. The PRI-MUS protocol was used to locate targets on microUS. Lesions with a PRI-MUS score ≥ 3 were targeted. All patients were also subjected to systematic prostatic biopsies. The presence of overall and of clinically significant PCa (defined as a Gleason score ≥ 7 cancer; csPCa) was determined. The proportion of patients who were excluded from AS either for upgrading to csPCa or for increasing number of positive cores (≥ 2) at confirmatory biopsies was determined, and the diagnostic performance of microUS in this setting was determined.

Results: Median patient age was 65 (IQR 60–71) years, median total PSA was 7.1 (IQR 5.1 – 9.5) ng/mL and median prostate volume was 47.7