(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 ≥ s4 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.

SC44 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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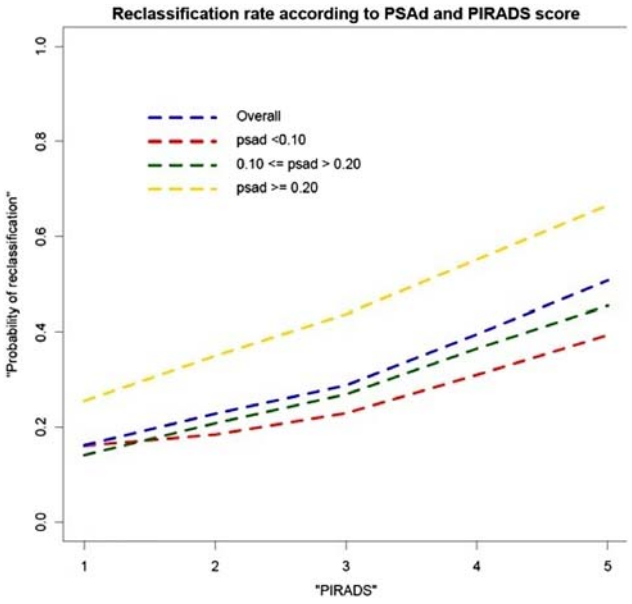
Aim of the study: Multiparametric (mp)MRI is increasingly used in the management of patients in Active Surveillance (AS). The aim of the study is to evaluate the rate of reclassification in men in AS, stratified on the basis of PI-RADS lesions and PSA-density (PSAD).
Materials and methods: F rom 01/2016 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 ≥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 μm. 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

(IQR 39–66) mL. Overall, 13 (19.1%) patients had a cT2a PCa. MicroUS detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 13 (19.1%), 38 (55.9%) and 9 (13.2%) patients, while in 8 (11.8%) individuals microUS did not identify any target. Prostate cancer detection rate was 66.2% (n = 45). Among patients diagnosed with PCa, 23 (51.1%) were upgraded to a GS ≥7 cancer, while 4 (8.9%) showed more than 2 cores at confirmatory biopsy, resulting in 27 (39.7%) individuals who were excluded from AS. Of note, the proportion of patients who were excluded from AS significantly increased from 12.5% in patients with a negative microUS to 23.1%, 42.1% and 77.8% in patients having a PRIMUS 3, 4 and 5 lesion, respectively (p = 0.023). The diagnostic performance of microUS for detecting individuals excluded from AS was the following: sensibility: 96.2%, specificity: 20.5%, negative predictive value: 87.5%, and positive predictive value: 43.3%.

Discussion: According to this preliminary experience, microUS may represent a promising new imaging modality showing high sensitivity to detect csPCa and who may be subsequently excluded from AS. In addition, this diagnostic tool appears to be capable of reliably excluding the presence of csPCa in the great majority of patients. However, large-scale efforts are still needed to provide further evidences supporting the adoption of microUS in patients enrolled in AS protocols.

SC46 Cancer specific anxiety and depression levels in localized low-risk prostate cancer who choose active surveillance or radical treatment: Findings from the START study

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Aim of the study: Some Authors report that anxiety surrounding disease progression could play a significant role in influencing long term adherence to active surveillance (AS) protocols for localized low-risk prostate cancer (LRPCa). Aim of our study was to evaluate the difference in terms of anxiety in men with LRPCa who choose AS instead of radical treatment [RTr] (radical prostatectomy [RP] or radiotherapy). Furthermore, we evaluated if anxiety levels changed during the follow-up.

Materials and methods: Data of patients enrolled in the START study until the 15th of March 2019 were evaluated. Anxiety scores, measured by the Hospital Anxiety Depression Scale (HADS), range from a minimum of 7 (no anxiety) to a maximum of 21 (maximum value of anxiety); a score between 8–10 indicates a borderline level of anxiety, above 10 a pathological value of anxiety. The difference between the 24-months anxiety score and the baseline score was analyzed. Statistical analysis was performed using the t test and the regression logistic model.

Results: The sample analyzed was composed of 507 patients. 407 patients (80,3%) chose AS, whilst 100 patients (19,7%) chose RTr. Concerning patients who chose AS, the mean age was 69.7 (+7.0) yrs. PSA was >7 ng/ml in 91 and Gleason Score was 3 + 4 in 55 patients. The histological review was performed in 126 patients. 113 patients chose AS after a multidisciplinary consultation. Concerning patients who chose RTr, the mean age was 67.8 (+5) yrs. PSA was >7 ng/ml in 32 and Gleason Score was 3 + 4 in 24 patients. The histological review was performed in 17 patients. 8 patients chose radical treatment after a multidisciplinary consultation. Regression logistic models showed that the major variables related to the choice of AS were: Charlson Score >2 (OR 2.46, p 0.0193), being submitted to a multidisciplinary consultation (OR 4.144, p 0.0004), being submitted to an urological consultation (OR 2.28, p 0.0423) and having performed an histological review (OR 2.022, p 0.0234). The major variables related to the choice of RTr were: T2a clinical stage (OR 0.479, p 0.0243), >2 cores involved by the tumor (OR 0.540, p 0.0162), and a GS 3 + 4 (OR 0.362, p 0.0041). The results of the HADS questionnaire were analyzed comparing the 2 most represented groups (AS and RP). The results are shown in the graphs 1 and 2. The average anxiety scores did not differ at the baseline, after 6 months and after 18 months in the 2 groups (p 0.605, 0.635, 0.526 respectively). On the contrary, a slight decrease in anxiety score was found at 12 months and a slight increase was registered at 24 months in patients who chose RP (p 0.08 and 0.161 respectively). Considering depression, our results showed a slight increasing trend in patients who chose RP after 18 and 24 months of follow-up (p 0.805 and 0.403 respectively).

Discussion: In patients with LRPCa, anxiety rates were very similar at the moment of choice between AS and RP and did not change after 24 months.