estimated 13.4% risk of csPCa. External validation of our model is needed.

SC39 Development of novel criteria for active surveillance based on multiparametric MRI alone in men with Gleason 3 + 4 prostate cancer: Use of imaging to safely expand the eligibility for active surveillance

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Aim of the study: Clinical guidelines recommend active Surveillance (AS) in men with low-risk prostate cancer (PCa) and in some highly selected low-volume Gleason 3 + 4 within a prospective protocol. However, the latter recommendation is based on results obtained in the pre-MRI era. We hypothesized that mpMRI characteristics might assist physicians in the identication of Gleason 3 + 4 patients suitable for AS regardless of the number of positive scores.
Materials and methods: Overall, 309 patients with Gleason 3 + 4 PCa at biopsy who underwent MRI-targeted biopsy plus systematic cores and radical prostatectomy (RP) between 2016 and 2018 were identied. Prostate biopsy and prostatectomy specimens were evaluated by dedicated uro-pathologists. Misclassication was dened as non-organ conned or ISUP grade group ≥3 disease at RP. Multivariable logistic regression analyses assessed the association between mpMRI parameters (i.e., extracapsular extension [ECE] and maximum lesion diameter) and misclassication after adjusting for confounders. The diameter of the lesion at mpMRI was dichotomized according to the most informative cut-off predicting misclassication. A novel risk classication was proposed based clinical characteristics and mpMRI ndings. A comparison of the proportion of patients eligible for AS and the rates of misclassication was performed between men selected for AS according to the new imaging criteria vs. established criteria of low volume Gleason 3 + 4 (≤2 positive cores).
Results: Median lesion diameter was 8 mm and 39 (13.2%) patients had suspicious ECE at mpMRI. Overall, 185 (59.9%) patients experienced misclassication. At multivariable analyses, ECE at mpMRI ($p = 0.03$) and lesion diameter ($p = 0.01$) were associated with the risk of misclassication. The ROC-derived area under the curve of the model was 75%. The most informative cut-off of lesion diameter for misclassication was 12 mm. Patients without ECE at mpMRI and with a lesion <12 mm were classied as low risk regardless of the number of positive cores. The proportion of patients potentially eligible for AS increased from 18.1 to 22.5% when adopting the new mpMRI criteria compared to the inclusion of only men with 1–2 positive cores. The rate of misclassication was lower in intermediate-risk patients selected according to the new mpMRI criteria vs. those selected according to the number of positive cores (44.6 vs. 53.6%).
Discussion: Information obtained at mpMRI can assist physicians in the identication of men with Gleason 3 + 4 more likely to experience misclassication. Men with biopsy Gleason 3 + 4 without ECE and with a lesion <12 mm at mpMRI biopsy could be included in AS protocols regardless of the number of positive cores at biopsy thus expanding AS indications while decreasing the rates of misclassication at the same time.

SC40 The role of magnetic resonance in active surveillance for prostate cancer. The romas project: Four years experience in a randomized, prospective study

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Aim of the study: Multiparametric Magnetic Resonance Imaging (mpMRI) has joined increasing enthusiasm as a diagnostic tool able to identify clinically significant Pca (csPCa). However, the role of mpMRI for patients who are included in AS protocols is still a matter of debate. The aim of our study was to evaluate the impact of mpMRI in the early identification (within 3 months) of csPCa in patients fulfilling AS criteria.
Materials and methods: From May 2015 to March 2019, 93 very low and low risk PCa patients were included in our AS protocol. Inclusion criteria for AS were: 35–75 year-old men; diagnosis of PCa within 8 weeks; PSA ≤ 10 ng/ml; Clinical T1c or T2 assessed with DRE and TRUS; Gleason Score < 7; <3 positive cores; at least 12 biopsy cores taken; PSA density (PSAd) less or equal to 0.2; ASA score ≤ 3; central revision of the biopsy core confirming the presence of indolent Pca. Patients were randomized (1:1) in two groups: group 1 (n = 38) were given an mpMRI at 3 months from the beginning of AS; group 2 (control group, n = 33) did not receive the mpMRI within 12 months of surveillance. Patients in both Groups had a PSA dosage every 3 months and underwent digital rectal examination (DRE) every 6 months. In group 1, patients with at least one PIRADS ≥ 3 lesion at mpMRI underwent a Fusion biopsy (FB) plus systematic random biopsy; patients with negative mpMRI (namely PIRADS ≤ 2 lesion at mpMRI) in group 1 and patients included in group 2 underwent a confirmation systematic biopsy 12 months after the beginning of the study and subsequent prostate biopsy at 48 and 72 months. In case of reclassification (both due to upgrading and to upsizing) patients were scheduled for radical treatments (including radical prostatectomy or primary radiotherapy).
Results: Table 1 shows the clinical characteristics of the entire patient population. The two groups of patients were comparable in terms of initial Age, PSA, PSA density, clinical stage, number of positive and total cores. Table 2 shows the percentage of reclassified patients at 3 and 12 months. Of the 48 patients who underwent mpMRI at 3 months, 14 (26.9%) had at least one significant lesions nine of these patients (18.7%) were reclassified: 8 (87.5%) men due to upgrading and 1 patient due to upsizing. At 12-month random re-biopsy, only 2 out of 25 patients in group 1 (8%) and 11 out of 33 patients in group 2 (33%) were reclassified ($p = 0.03$). Kaplan-Meyer plots (figure 3) estimate active treatment free survival among the 2 groups.
Discussion: The early implementation of a mpMRI into an AS protocol was able to obtain earlier reclassification rates and to significantly reduce the percentage of patients who would be reclassified at 12 months with a systematic biopsy. Therefore, our data suggest to include a mpMRI in AS protocols in order to offer timely radical treatments in patients with csPCA. A larger study population and longer follow up may help to achieve more accurate results.