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.
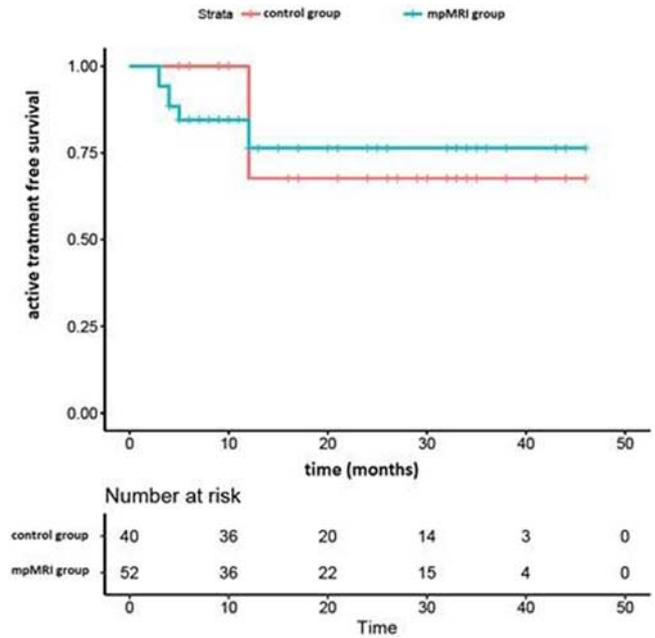
Table 1. Characteristics of the general population

Variable	Global	Control Group	mpMRI Group	p value
Number of Patients (%)	93 (100)	42 (45)	51 (55)	-
Age Median (IQR)	65 (61-70)	65 (62-70)	65 (59-70)	0.4
PSA at diagnosis (ng/ml) Median (IQR)	6 (4.7-7.3)	6.3 (4.7-7.3)	5.9 (4.8-7.2)	0.7
Prostate volume at TRUS (cc) Median (IQR)	51 (36-67)	60 (49.5-72.5)	47 (35-63)	0.004
PSA density (ng/ml/cc) Median (IQR)	0.12 (0.09-0.15)	0.1 (0.08-0.12)	0.11 (0.10-0.16)	0.08
Clinical Stage, n (%) T1c T2a T2b T2c	83 (89.2) 9 (9.7) 0 (0) 1 (1.1)	37 (88.1) 4 (9.5) 0 (0) 1 (2.4)	46 (90.2) 5 (9.8) 0 (0) 0 (0)	0.5
Number of biopsy cores Median (IQR)	12 (12-13)	12 (12-14)	12 (12-13)	0.8
Number of positive biopsy cores Median (IQR)	1 (1-1)	1 (1-1)	1 (1-1)	0.7
Number of patients with ≥ 2 positive cores at first prostate biopsy, n (%)	18 (19.4)	9 (21.4)	9 (17.6)	0.8

Table 2. Reclassification between the two groups

Variable	Control Group	mpMRI Group	p value
mpMRI performed (<12 weeks), n (%)	-	48 (92.3)	-
Positive mpMRI, n (%)	-	14 (29.1)	-
PIRADS v-2 3 4 5	-	9 (18.7) 4 (8.3) 1 (2)	-
Reclassification after mpMRI and FUSION biopsy at 12 weeks, n (%)	-	9 (18.5)	-
Number of cores FUSION biopsy Mean±SD	-	9±5	-
Number of positive cores at FUSION biopsy Mean±SD	-	3±2	-
Bioptic Gleason score at FUSION Biopsy Negative 3+3 3+4 4+3 4+4	-	1 (7) 5 (35.7) 2 (14.2) 4 (28.6) 2 (14.2)	-
PSA at 3 months Mean±SD	5.6±2.9	5.9±2.5	0.7
PSA density at 3 months (ng/ml/cc) Mean±SD Median (IQR)	0.1±0.09 0.09 (0.06-0.11)	0.12±0.06 0.11 (0.08-0.16)	0.4 0.04
PSA at 6 months Mean±SD	6.4±3.3	5.8±2.8	0.7
PSA at 9 months Mean±SD	5.3±2	6.1±2.7	0.2
PSA a 12 mesi Mean±SD	5.9±2.2	5.9±3	0.9
PSA density at 12 months (ng/ml/cc) Mean±SD Median (IQR)	0.1±0.1 0.1 (0.08-0.12)	0.1±0.04 0.1 (0.07-0.12)	0.7 0.8
Reclassification after re-biopsy at 12 months, n (%)*	11/33 (33.3)	2/25 (8)	0.03
Number of re-biopsy cores at 12 months * Mean±SD	13±1.6	13±1.2	0.05
Number of re-biopsy positive cores at 12 months * Mean±SD	0 1.4±1.6	0.8±1.2	0.2
Gleason score re-biopsy at 12 months* Negative 3+3 3+4 4+3 4+4 4+5	14 (41.2) 11 (32.4) 6 (17.6) 1 (2.9) 1 (2.9) 1 (2.9)	15 (60) 9 (36) 1 (4) 0 (0) 0 (0) 0 (0)	0.4

* excluding patients reclassified with mpMRI at 12 weeks

SC41 **Utility of mpMRI/transrectal US fusion confirmatory biopsy in men with a previous diagnosis of prostate cancer amenable to active surveillance**

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Aim of the study: Recently, the ASIST trial demonstrated that the addition of MRI-targeted biopsies to systematic biopsies did not significantly increase the upgrading rate compared with systematic biopsy alone. The aim of the present study is to compare the diagnostic accuracy of mpMRI/transrectal US fusion (FB) to standard transrectal random biopsy (RB) in the setting of confirmatory/per protocol biopsy during AS.

Materials and methods: From November 2016 to February 2019, 87 patients under AS for NCCN very low or EAU/NCCN low-risk PCa had a positive mpMRI (PIRADS v2 ≥ 3) and subsequently underwent mpMRI/transrectal US FB with Hitachi RVS system and concurrent transrectal 24-cores RB at a single academic institution. The two biopsy procedures were performed by two separate operators, keeping the RB operator unaware of the results of mpMRI and the location of the FB. All MRI scans were performed at our institution by two dedicated uro-radiologists or reviewed by one of the 2 dedicated uro-radiologist and PIRADS re-assigned if performed elsewhere. Each core was processed with sandwich technique in a single biobox and examined by a single dedicated uro-pathologist. Clinically significant PCA (CSPCa) was defined as in the PROMIS trial (i.e. Gleason score ≥4 + 3 or a maximum cancer core length 6 mm or longer). Statistical analyses were performed with SPSS v.24.0 software. Continuous variables were reported as median and interquartile range (IQR). K statistic was used to assess the Gleason score concordance between FB and RB.

Results: Median age at biopsy was 67 year (IQR 60–73) and median total PSA was 6,0 ng/ml (IQR 4,6–8,6), with a median prostate volume at US of 55 ml (IQR 40–76). PIRADS score was 3 in 24%, 4 in 55% and 21% of the patients, respectively. Overall PCa presence was reconfirmed in 77% of the cases. Specifically, in 35 patients both FB and RB were