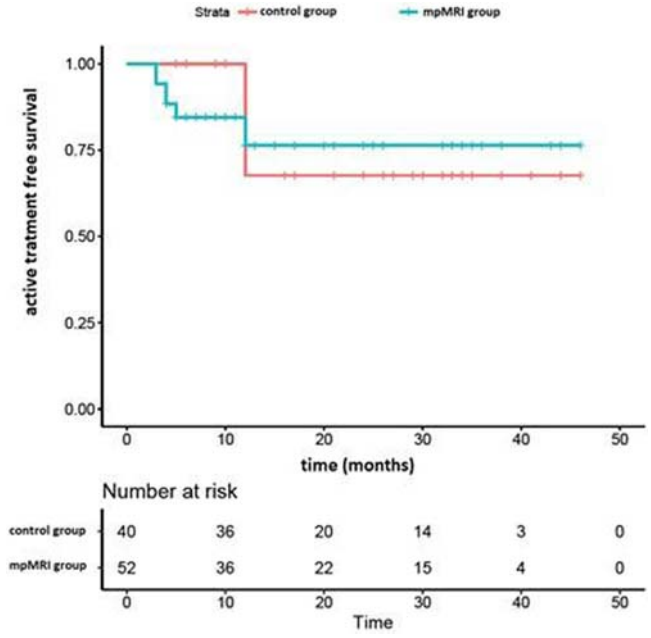
Table 1. Characteristics of the general population

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 5 in 21% of the patients, respectively. Overall PCa presence was reconfirmed in 77% of the cases. Specifically, in 35 patients both FB and RB were

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.

SC42 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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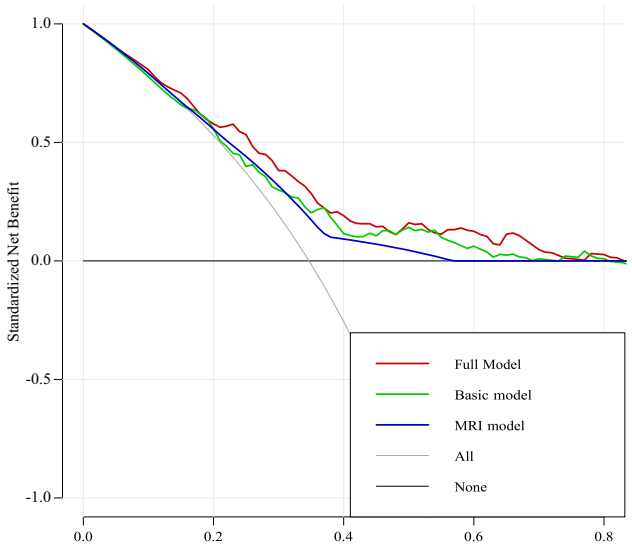
Aim of the study: The aim of the study is to evaluate whether mpMRI alone could be used as a stand-alone test suggesting risk of reclassification in men in AS.
Materials and methods: We retrospectively evaluated 399 pts undergoing confirmatory or follow-up biopsy according to PRIAS protocol, from January 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 clincial 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.

SC43 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 $\leq$ 3 and PI-RADS $\geq$ 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