OBJECTIVE: The objective of this study is to determine the frequency of clinically significant cancer (CSC) in Prostate Imaging Reporting and Data System (PI-RADS) category 3 (equivocal) lesions prospectively identified on multiparametric prostate MRI and to identify risk factors (RFs) for CSC that may aid in decision making.

MATERIALS AND METHODS: Between January 2015 and July 2016, a total of 977 consecutively seen men underwent multiparametric prostate MRI, and 342 underwent MRI-ultrasound (US) fusion targeted biopsy. A total of 474 lesions were retrospectively reviewed, and 111 were scored as PI-RADS category 3 and were visualized using a 3-T MRI scanner. Multiparametric prostate MR images were prospectively interpreted by body subspecialty radiologists trained to use PI-RADS version 2. CSC was defined as a Gleason score of at least 7 on targeted biopsy. A multivariate logistic regression model was constructed to identify the RFs associated with CSC.

RESULTS: Of the 111 PI-RADS category 3 lesions, 81 (73.0%) were benign, 11 (9.9%) were clinically insignificant (Gleason score, 6), and 19 (17.1%) were clinically significant. On multivariate analysis, three RFs were identified as significant predictors of CSC: older patient age (odds ratio [OR], 1.13; \( p = 0.002 \)), smaller prostate volume (OR, 0.94; \( p = 0.008 \)), and abnormal digital rectal examination (DRE) findings (OR, 3.92; \( p = 0.03 \)). For PI-RADS category 3 lesions associated with zero, one, two, or three RFs, the risk of CSC was 4%, 16%, 62%, and 100%, respectively. PI-RADS category 3 lesions for which two or more RFs were noted (e.g., age \( \geq 70 \) years, gland size \( \leq 36 \) mL, or abnormal DRE findings) had a CSC detection rate of 67% with a sensitivity of 53%, a specificity of 95%, a positive predictive value of 67%, and a negative predictive value of 91%.

CONCLUSION: Incorporating clinical parameters into risk stratification algorithms may improve the ability to detect clinically significant disease among PI-RADS category 3 lesions and may aid in the decision to perform biopsy.

KEYWORDS: MRI-ultrasound fusion targeted biopsy; PI-RADS category 3 lesions; PI-RADS version 2; prostate cancer; prostate multiparametric MRI