

Establishing the Best Threshold for Biopsy in mpMRI Negative or Indeterminate Men using Data from a Large Multi-Institutional Cohort of Men undergoing mpMRI, 4Kscore and Prostate Biopsy

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Introduction and Objective:

Multi parametric MRI (mpMRI) has emerged as the most common tool to evaluate the need for biopsy in men referred for suspicion of prostate cancer, however PIRADS 3 or indeterminate findings remain a controversy and the rate of missed cancer on negative mpMRI remains a concern. We evaluated a large multi-institutional dataset to identify the best 4Kscore threshold to determine the need for a biopsy when the mpMRI is negative or PIRADS 3.

Methods:

We retrospectively evaluated men in 8 different institutions who underwent an mpMRI, 4Kscore, and prostate biopsy for evaluation of prostate cancer. We selected men who were found to have negative or PIRADS 1-3 mpMRI's. The mpMRI was categorised as Negative/PIRADS 1-2 or PIRADS 3. The 4kscore is reported as a continuous score and categorised into 4 levels of incremental risk. We evaluated the proportion of men with grade group 2 or higher (GG2+) cancer in each PIRADS and 4Kscore category. In addition, we used logistic regression to create an mpMRI-4KScore based model and report the predicted probability of GG2+ cancer in each PIRADS and 4Kscore category.

Results:

Among 1111 men who had a mpMRI, 4Kscore, and biopsy, 625 of them had PIRADS 1-3 on mpMRI (negative/PIRADS 1-2: 374, PIRADS 3: 251). When the mpMRI was negative or PIRADS 1-2, the proportion of GG2+ cancer was less than 20% for each 4Kscore category except those with a 4Kscore above 32% who had a 31% risk of GG2+ cancer. Similarly, the upper limit of the 95% confidence interval for the predicted probability of GG2+ cancer was less than 20% in each 4Kscore category except those with a 4Kscore above 34% (Table 1). Alternatively, when the mpMRI reported PIRADS 3, the probability of GG2+ cancer was above 20% in each 4Kscore category except those with a 4Kscore below 8%. Likewise, the predicted probability of GG2+ cancer was close to 20% or higher in each 4Kscore category (with the lower limit of the 95% confidence interval above 13%) except those with a 4Kscore below 8% (Table 1).

Conclusions

We evaluated men with negative or PIRADS 1-3 mpMRI and found the when the mpMRI was negative or PIRADS 1-2 the best 4Kscore threshold to decide on the need for a biopsy was 32%. However, when the mpMRI was PIRADS 3, a

4Kscore of 8% or higher was best for deciding on the need for a biopsy. These findings need further validation in prospective studies.

PIRADS	4KScore range (%)			
	1-7	8-19	20-32	>32
0-2	1/104 (1%)	9/146 (6.2%)	5/56 (8.9%)	21/68 (30.9%)
	1.4% (0.7- 2.7%)	7.9% (5.4- 11.6%)	10.3% (6.6- 15.8%)	25.2% (18.4- 33.6%)*
3	3/75 (4%)	20/92 (22%)	9/40 (23%)	19/44 (43%)
	3.7% (2.0- 6.9%)**	19.1% (13.8- 25.8%)	23.9% (16.6- 33.2%)	48.0% (38.2- 57.8%)

Table 1. Observed number (%) and predicted % (95% confidence interval) of GG2+ cancer

*Note the 95% CI for this 4Kscore level does not overlap with others suggesting a statistically significant difference

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