A Multi-Institutional Study of 1111 Men With 4Kscore, Multiparametric MRI and Prostate Biopsy

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Introduction and Objective:
We evaluated effectiveness of mpMRI and 4K score in a multi-site trial individually and together for detection of clinically significant prostate cancer and to reduce unnecessary biopsies.

Methods/Materials:

We retrospectively evaluated men in 8 different institutions who were referred for prostate cancer evaluation and underwent mpMRI ,4Kscore test and prostate biopsy. The primary outcome was the presence of grade group 2 or higher cancer on biopsy of the prostate. We examined individually and various combinations and sequences of mpMRI and 4Kscore test and assessed the impact on biopsies avoided and cancers missed. We used logistic regression and decision curve Analysis to report the discrimination and clinical utility of using mpMRI and the 4Kscore test for prostate cancer detection.

Test Strategies

Strategy	Decision for biopsy
T1[1]	Score >8%
T2[2]	PIRADS 3-5
T3[3]	PIRADS 4-5 (high risk) or 4K score >= 8-19% (intermediate or high risk).
T4[4]	4K score >=20% (high risk by 4k), or if PIRADS 3 or 4-5 (intermediate or high risk by mpMRI).
T5[5]	PIRADS 4-5 (high risk by mpMRI), or if 4K score >= 20% (high risk by 4K).

Table 1

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[1] T1- 4K score in all subjects
[2] T2- mpMRI in all subjects
[3] T3- Both tests mpMRI and or 4K score
[4] T4- 4Kscore (test 1) +mpMRI (test 2, if intermediate risk by 4K score 8-19%)
[5] T5- mpMRI (test 1) + 4K score (test 2, if low or intermediate risk by mpMRI PIRADS 0-3)

Results:

Among 1111 men who underwent a 4Kscore test and mpMRI, 553 (49.8%) had cancer grade group (GG) greater or equal to 1 (GG1+), 353 (31.8%) were cancer GG greater or equal to 2 (GG2+).

When we used sequential test strategy, there was a higher reduction in biopsy as compared to single test strategy with equivalent proportion of GG2+ cancers missed which were mostly grade group 2 or 3. Also, when we used both tests together, we did more biopsies as compared to single test but missed very low GG2+ cancers (1.1%). Decision analysis revealed the highest net benefit was achieved using both tests in figure 1.

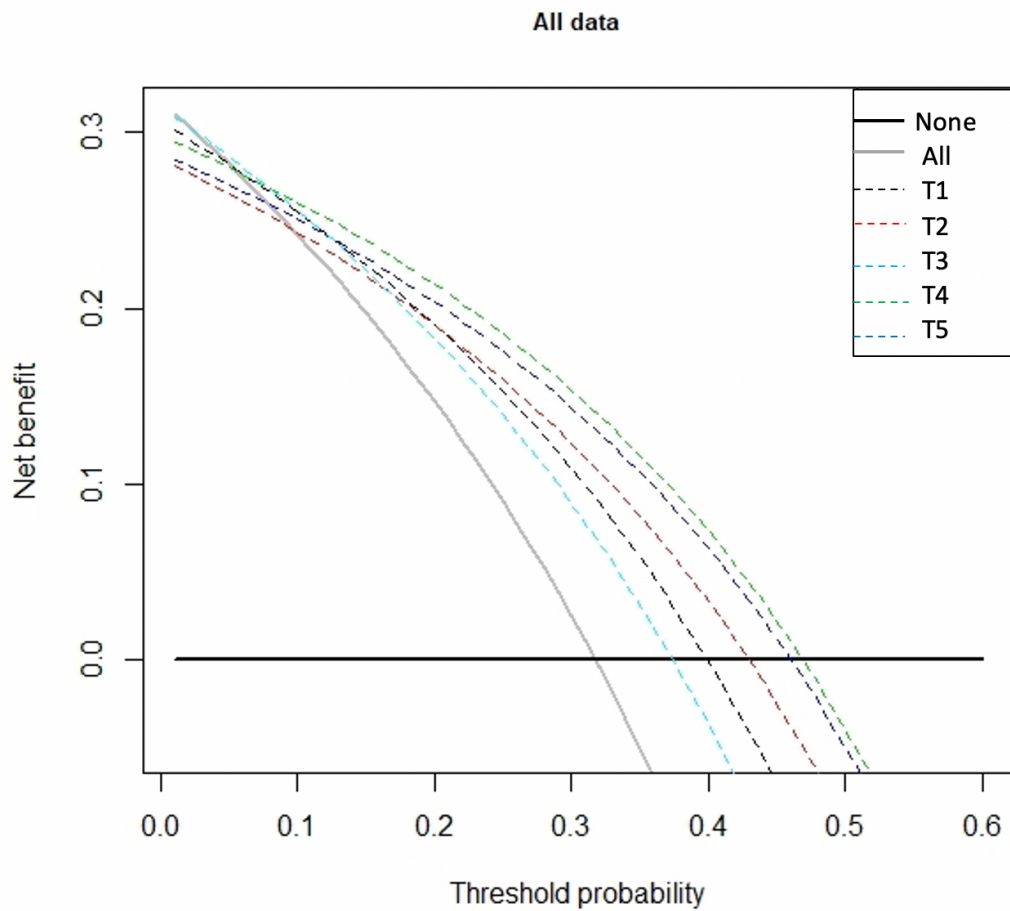| Test Strategy	Biopsy (%)	Biopsy reduction %	Area Under Curve (%)	GG2+ cancer undetected (%)
T1: Single test 4K	851 (76.6)	23.4	64.45	13 (3.7)
T2: Single test mpMRI	737 (66.3)	33.7	67.20	36 (10.2)
Combination tests:				
T3: mpMRI high or 4K int. or high	932 (83.9)	16.1	60.98	4 (1.1)
T4: 4K + mpMRI (if int. risk by 4K)	705 (63.5)	36.5	72.21	33 (9.3)
T5 mpMRI + 4K (if low/int. risk by mpMRI)	694 (62.5)	37.5	70.06	33 (9.3)

Table 2

Figure 1

Conclusions

Our study is the largest study reported till date which includes men who underwent 4K score, mpMRI and prostate biopsy. Optimal strategy to reduce unnecessary biopsies and avoid missing clinically significant prostate cancer cannot be concluded, further need prospective studies.