Prostate Health Index for risk stratification before magnetic resonance imaging: abridged secondary publication

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KEY MESSAGES

1. The use of multiparametric magnetic resonance imaging (MRI) and the Prostate Health Index (PHI) can improve risk stratification for men with elevated prostate-specific antigen levels.
2. Selectively avoiding MRI in men with lower PHI scores can reduce costs and unnecessary biopsies, while ensuring timely diagnosis of clinically significant prostate cancer.
3. Risk stratification based on PHI can optimise allocation of limited MRI resources and improve the efficiency of prostate cancer screening and early detection.

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Introduction

In Hong Kong public hospitals, the waiting time for magnetic resonance imaging (MRI) in patients with elevated prostate-specific antigen (PSA) levels can exceed 1 year. It is therefore important to allocate MRI resources to patients at higher risk of prostate cancer. The Prostate Health Index (PHI) has been shown to predict clinically significant prostate cancer in patients with a score of 3 or 4 in the Prostate Imaging Reporting and Data System (PI-RADS), but the role of PHI in predicting abnormal prostate MRI results is not well described.

Prostate cancer is the second most common cancer in men globally,[1] and its incidence is rapidly increasing in Asia, particularly in Hong Kong.[2] Diagnosis typically involves a prostate biopsy for those with high PSA levels, but this can lead to unnecessary biopsies and over-diagnosis.[3] In Hong Kong, blood testing for PHI is commonly used to assess those with high PSA levels.[3]

Multiparametric MRI can improve detection of clinically significant prostate cancer. It can guide targeted biopsies and reduce unnecessary ones, as demonstrated by the PROMIS and PRECISION trials. European guidelines recommend MRI before considering a biopsy for those with high PSA levels.[4] However, access to MRI is limited in Hong Kong public hospitals. Thus, it is important to focus resources on patients at higher risk. The role of PHI in predicting abnormal MRI results remains unclear. This study aimed to optimise allocation of MRI resources based on risk stratification in a cohort of Chinese men.

Methods

Consecutive Chinese men aged ≥18 years with PSA levels of 4 to 10 ng/mL, normal prostate findings on digital rectal examination, and a record of blood testing for the PHI were prospectively recruited from Prince of Wales Hospital and North District Hospital, Hong Kong. Participants underwent contrast-enhanced multiparametric MRI of the prostate; results were reported according to PI-RADS v2.1 criteria and scored from 1 to 5. The proportions of abnormal MRI results (PI-RADS 3-5) were compared among PHI ranges. Systematic and MRI-guided biopsies were offered to participants with PHI ≥35; for those with PHI <35, biopsies were offered only if MRI findings were abnormal (Fig).

The proportions of abnormal MRI results were analysed across PHI ranges. Various PHI cut-offs were evaluated for their association with PI-RADS scores of ≥3 or ≥4 and for the detection of any clinically significant prostate cancer (International Society of Urological Pathology [ISUP] grade ≥2 or Gleason score ≥7) on prostate biopsy.

Assuming that two-thirds of eligible patients would have PHI <35, and that abnormal MRI results would be observed in 15% of those with PHI <35 and 40% of those with PHI ≥35, a total of 143 men (95 with PHI <35 and 48 with PHI ≥35) were required to achieve 90% power and a 5% type I error. A sample size of 159 was targeted to account for an anticipated 10% withdrawal rate. All tests were two-sided; statistical significance was set at 0.05.

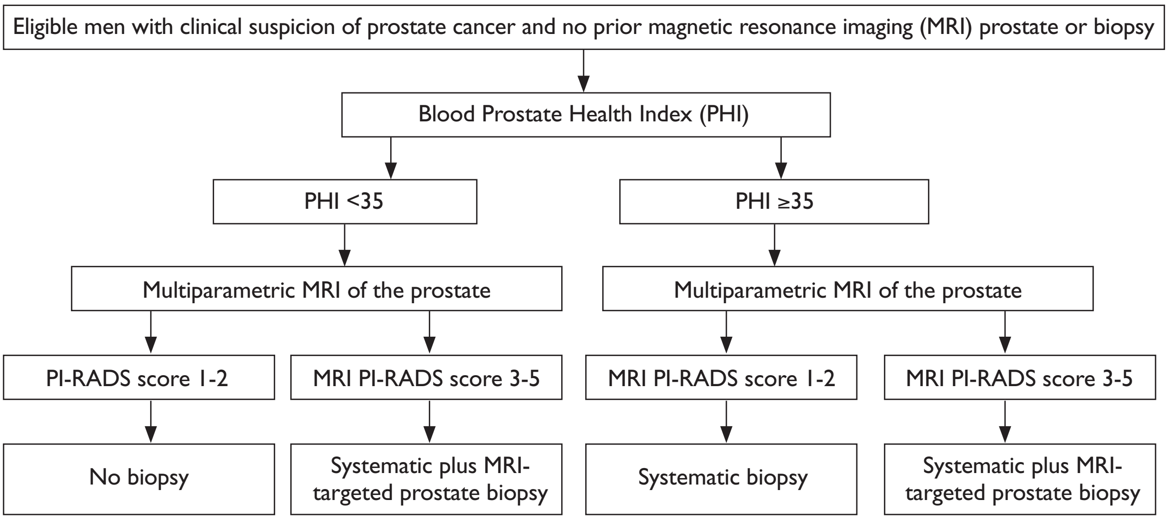

FIG. Trial schema.
Abbreviation: PI-RADS=Prostate Imaging Reporting and Data System

Results

In total, 159 men with elevated PSA levels (4-10 ng/mL) were recruited and underwent blood testing for PHI. Six (3.8%) men withdrew from the study before undergoing MRI. Of the 153 patients who completed prostate MRI, 55 had PHI ≥35 or MRI PI-RADS ≥3 and underwent prostate biopsy, except for one who declined. Among the 54 men who underwent biopsy, the median age was 69.0 (interquartile range [IQR], 64-73) years, the median PSA level was 5.7 (IQR, 4.8-7.0) ng/mL, the median PHI was 26.3 (IQR, 21.8-31.5), and the median prostate volume was 58.0 (IQR, 42.0-75.5) mL.

MRI findings of PI-RADS ≥3 were observed in 21.6% (27/125) of men with PHI <35 and 50.0% (14/28) of men with PHI ≥35 (P=0.002). MRI findings of PI-RADS ≥4 were observed in 9.6% (12/125) of men with PHI <35 and 35.7% (10/28) of men with PHI ≥35 (P<0.001) [Tables 1 and 2].

In terms of clinically significant prostate cancer detection, ISUP grade ≥2 prostate cancer was diagnosed in 6.4% (8/125) and 46.4% (13/28) of men with PHI <35 and PHI ≥35, respectively (P<0.001). ISUP grade ≥3 prostate cancer was diagnosed in 1.6% (2/125) and 25.0% (7/28) of men with PHI <35 and PHI ≥35, respectively (P<0.001). There was a sharp increase in ISUP grade ≥2 among those with PHI 30 to 34.9 (18.8%), compared with PHI <30 (4.6%) [Tables 1 and 2].

Among the 54 men who underwent biopsy, 11 (20.4%) experienced biopsy-related adverse events, including seven cases of haematuria, one case of haematospermia, one case of acute urinary retention (which occurred before biopsy), and two cases of post-biopsy urinary tract infection. The latter three events were categorised as severe adverse events.

Discussion

The PHI can be used to identify patients at higher risk of prostate cancer who require prostate MRI. This approach could prevent unnecessary MRI examinations and biopsies, conserving resources and reducing patient anxiety. Men with a PHI score ≥35 had a higher risk of prostate cancer, whereas men with a PHI score <25 had significantly lower rates of abnormal MRI results and prostate cancer. By omitting MRI in men with PHI scores <25, the number of MRI examinations could be reduced by 44.4% to 81.7%. However, men with PHI scores of 30 to 34.9 had a substantially higher risk of prostate cancer than those with scores <30. Thus, a PHI score of 30 may be a more appropriate threshold for determining the need for MRI.

The benefit of additional MRI was mainly observed among men with PSA levels of 4.0 to

TABLE 1. Proportions of patients with abnormal Prostate Health Index (PHI) in terms of various Prostate Imaging Reporting and Data System (PI-RADS) scores and International Society of Urological Pathology (ISUP) grades.

Baseline PHI	No. (%) of patients (n=153)				
	PI-RADS ≥3	PI-RADS ≥4	Prostate cancer	ISUP grade ≥2 prostate cancer	ISUP grade ≥3 prostate cancer
<25.0 (n=68)	15 (22.1)	8 (11.8)	9 (13.2)	4 (5.9)	0
25.0-29.9 (n=41)	8 (19.5)	2 (4.9)	2 (4.9)	1 (2.4)	1 (2.4)
30.0-34.9 (n=16)	4 (25.0)	2 (12.5)	3 (18.8)	3 (18.8)	1 (6.3)
35.0-44.9 (n=15)	7 (46.7)	5 (33.3)	6 (40.0)	5 (33.3)	4 (26.7)
45.0-54.9 (n=7)	3 (42.9)	1 (14.3)	4 (57.1)	2 (28.6)	0
≥55.0 (n=6)	4 (66.7)	4 (66.7)	6 (100)	6 (100)	3 (50.0)

TABLE 2. Stratification of patients with abnormal Prostate Health Index (PHI) using various PHI cut-offs, compared with various Prostate Imaging Reporting and Data System (PI-RADS) scores and International Society of Urological Pathology (ISUP) grades (n=153).

Stratification	PHI cutoff		P value	PHI cutoff		P value	PHI cutoff		P value
	<35 (n=125)*	≥35 (n=28)*		<30 (n=109)*	≥30 (n=44)*		<25 (n=68)*	≥25 (n=85)*	
PI-RADS ≥3	27 (21.6)	14 (50.0)	0.002	23 (21.1)	18 (40.9)	0.012	15 (22.1)	26 (30.6)	>0.05
PI-RADS ≥4	12 (9.6)	10 (35.7)	<0.001	10 (9.2)	12 (27.3)	0.004	8 (11.8)	14 (16.5)	>0.05
Prostate cancer	14 (11.2)	16 (57.1)	<0.001	11 (10.1)	19 (43.2)	<0.001	9 (13.2)	21 (24.7)	>0.05
ISUP grade ≥2 prostate cancer	8 (6.4)	13 (46.4)	<0.001	5 (4.6)	15 (34.1)	<0.001	4 (5.9)	17 (20.0)	0.032
ISUP grade ≥3 prostate cancer	2 (1.6)	7 (25.0)	<0.001	1 (0.9%)	8 (18.2)	<0.001	0	9 (10.6)	0.004

* Data are presented as No. (%) of patients.

10.0 ng/mL. The number of MRI examinations required to diagnose one additional case of ISUP grade ≥2 prostate cancer was 20 in men with PHI ≥35 and 94 in men with PHI <35. Among all men with PSA ≥4.0 ng/mL, 45.4% (89/196) avoided unnecessary biopsy through the combined use of PHI and MRI. A screening algorithm incorporating PSA, PHI, and MRI could effectively detect clinically significant prostate cancer while reducing unnecessary biopsies; the PHI served as an important step in risk stratification for prostate cancer screening.[5]

This study had some limitations, including a relatively small sample size and the fact that not all men with PHI <35 and negative MRI findings underwent prostate biopsy.

Conclusions

The PHI can serve as a routine biomarker to stratify the risk of abnormal MRI results and clinically significant prostate cancer in men with elevated PSA levels. Balancing MRI utilisation against the risk of missed diagnoses, MRI can be safely avoided in men with PHI <30.

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