The combined role of MRI prostate and prostate health index in improving detection of significant prostate cancer in a screening population of Chinese men.

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Using prostate-specific antigen (PSA) for prostate cancer (PCa) screening led to overinvestigation and overdiagnosis of indolent PCa. We aimed to investigate the value of prostate health index (PHI) and magnetic resonance imaging (MRI) prostate in an Asian PCa screening program. Men aged 50-75 years were prospectively recruited from a community-based PSA screening program. Men with PSA 4.0-10.0 ng ml-1 had PHI result analyzed. MRI prostate was offered to men with PSA 4.0-50.0 ng ml-1. A systematic prostate biopsy was offered to men with PSA 4.0-9.9 ng ml-1 and PHI [greater-than or equal to]35, or PSA 10.0-50.0 ng ml-1. Additional targeted prostate biopsy was offered if they had PI-RADS score [greater-than or equal to]3. Clinically significant PCa (csPCa) was defined as the International Society of Urological Pathology (ISUP) grade group (GG) [greater-than or equal to]2 or ISUP GG 1 with involvement of [greater-than or equal to]30% of total systematic cores. In total, 12.8% (196/1536) men had PSA [greater-than or equal to]4.0 ng ml-1. Among 194 men with PSA 4.0-50.0 ng ml-1, 187 (96.4%) received MRI prostate. Among them, 28.3% (53/187) had PI-RADS [greater-than or equal to]3 lesions. Moreover, 7.0% (107/1536) men were indicated for biopsy and 94.4% (101/107) men received biopsy. Among the men received biopsy, PCa, ISUP GG [greater-than or equal to]2 PCa, and csPCa was diagnosed in 42 (41.6%), 24 (23.8%), and 34 (33.7%) men, respectively. Compared with PSA/PHI pathway in men with PSA 4.0-50.0 ng ml-1, additional MRI increased diagnoses of PCa, ISUP GG [greater-than or equal to]2 PCa, and csPCa by 21.2% (from 33 to 40), 22.2% (from 18 to 22), and 18.5% (from 27 to 32), respectively. The benefit of additional MRI was only observed in PSA 4.0-10.0 ng ml-1, and the number of MRI needed to diagnose one additional ISUP GG [greater-than or equal to]2 PCa was 20 in PHI [greater-than or equal to]35 and 94 in PHI <35. Among them, 45.4% (89/196) men with PSA [greater-than or equal to]4.0 ng ml-1 avoided unnecessary biopsy with the use of PHI and MRI. A screening algorithm with PSA, PHI, and MRI could effectively diagnose csPCa while reducing unnecessary biopsies. The benefit of MRI prostate was mainly observed in PSA 4.0-9.9 ng ml-1 and PHI [greater-than or equal to]35 group. PHI was an important risk stratification step for PCa screening.

Introduction

Prostate cancer (PCa) is the second-most common male cancer in the world,[1] and its incidence in the Asia-Pacific region is increasing.[2] While serum prostate-specific antigen (PSA) level remains the most common marker for screening or early diagnosis of PCa, its specificity is very low. In the European Randomized Study of Screening for Prostate Cancer (ERSPC), PSA-based screening have resulted in reduced prostate cancer-specific death and metastasis, and the number needed to screen (NNS) to prevent one prostate cancer death gradually reduced with longer follow-up time from 1410 to 570 at 16 years.[3] However, problems like overbiopsy (and associated complications), overdiagnosis of indolent prostate cancers, and overtreatment still exist.[4],[5],[6],[7] These limit population-wide PCa screening around the world.

The blood test prostate health index (PHI) is a formula incorporating PSA, free PSA, and [-2]proPSA (p2PSA), and it provides better prostate cancer risk stratification than PSA in men with elevated PSA level of 4.0-10.0 ng ml-1.[8] Using PHI 35 as a cutoff value in Chinese men, the International Society of Urological Pathology (ISUP) grade group (GG) [greater-than or equal to]2 PCa was found in only 0.7% in men of PHI <35, but up to 8.6% in men of PHI [greater-than or equal to]35 on systematic biopsies, with a 12-fold difference.[9] The use of PHI test could significantly reduce unnecessary prostate biopsies, and the PHI test has been regularly performed in the public healthcare system in Hong Kong (China) for men with PSA 4.0-10.0 ng ml-1 since 2016.

According to the Prostate MR Imaging Study (PROMIS) trial, performing multiparametric magnetic resonance imaging (MRI) prostate

before an initial prostate biopsy in a clinical Caucasian cohort improved diagnosis of significant PCa by 18% while reducing 27% unnecessary biopsies.[10] Another Caucasian study of European men in the 5th round of screening in the ERSPC showed that adding MRI prostate could avoid 65% biopsies and 68% insignificant prostate cancer while detecting an equal percentage of significant cancers.[11] In a recently published meta-analysis, a biparametric (using only T2-weighted [T2W] and diffusion-weighted imaging [DWI] sequences without contrast) MRI prostate has similar performance compared with a standard multiparametric MRI prostate while reducing scanning time, use of contrast, and cost.[12]

Despite the promising results of PHI and MRI in improving the diagnostic accuracy of PCa, there are few studies assessing the additional role of these new diagnostic tools in screening population. Therefore, in this PCa screening study in Chinese men, we have incorporated PHI and biparametric MRI prostate, for patients with elevated serum PSA. The role of PHI and MRI prostate in improving detection of significant PCa would then be investigated.

Participants and Methods

Study design

This is a community-based multi-cancer screening study in Hong Kong (China) that involves two rounds of biannual screening of prostate, breast, and colorectal cancer.

The screening program was advertised through newspaper, radio, and television, and participants who were interested to join the screening program could register through a dedicated website, by phone or walk-in. They were then contacted by trained personnel by phone to confirm eligibility for cancer screening using the following criteria.

Inclusion criteria were the age of 50-75 years; and screening naÃ¯ve, defined as no blood taking for PSA, PHI, MRI prostate, or prostate biopsy in the past 5 years. Exclusion criteria were hematuria; or history of prostate cancer; or limited life expectancy (<10 years) estimated by the Charlson comorbidity index.

The standard screening pathway for PCa screening in this study involved blood taking (6 ml) for PSA in men, and automatic testing for PHI in the same blood sample if PSA was between 4.0 ng ml-1 and 10.0 ng ml-1. Men were divided into four groups according to PSA and PHI: Group 1 (PSA <4.0 ng ml-1), Group 2 (PSA 4.0-9.9 ng ml-1 and PHI <35), Group 3 (PSA 4.0-9.9 ng ml-1 and PHI [greater-than or equal to]35), and Group 4 (PSA 10.0-50.0 ng ml-1). A biparametric MRI prostate (T2W and DWI sequences only) was offered to all men with PSA between 4.0 ng ml-1 and 50.0 ng ml-1 as an additional side study. The study was approved by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee (Approval No. CRE-2018.495) and was registered on clinicaltrials.gov (NCT03891732). All participants provided written informed consent. The study was conducted according to the Declaration of Helsinki.

Men who were contraindicated for MRI (pacemaker or metallic implants which were not MRI-compatible or claustrophobia) were excluded from this MRI prostate side study. MRI prostate was reported by radiologists (WCWC, CCMC, and HYH) with experience in reporting more than 300 MRI prostates. The screening pathway with MRI prostate incorporated is shown in [Figure 1]. Prostate Imaging-Reporting and Data System (PI-RADS) was used to report MRI prostate results. Prostate biopsy (systematic with or without targeted if PI-RADS score 3-5) was offered for all men in Groups 3 and 4, and also men in Group 2 with MRI PI-RADS score 3-5.{Figure 1}

Biopsy protocol

All prostate biopsies were performed in the Prince of Wales Hospital, the Chinese University of Hong Kong (Hong Kong, China) by experienced urologists (PKFC, JYCT, and CFN) under pure local anesthesia. Fleet enema and one dose of prophylactic antibiotic (1 g, oral amoxicillin/clavulanic acid) was given before biopsy. Patients in Group 3 and Group 4 without MRI lesion (PI-RADS score 1-2) received systematic prostate biopsy of at least 10 cores. In men with suspicious MRI lesion (PI-RADS score 3-5), a targeted (3-4 cores per target) plus systematic biopsy (at least 10 cores) was performed using the MRI-Ultrasound fusion platform. Transrectal prostate biopsy was performed between October 2018 and June 2019. Transperineal prostate biopsy under local anesthesia was performed since July 2019 after a change of practice in the hospital with the aim to reduce biopsy-related infections.

Pathological assessments were performed by experienced uro-pathologists. ISUP GG and the number of cancerous cores were reported. Cancer outcomes included PCa, ISUP GG [greater-than or equal to]2 PCa, and clinically significant PCa (csPCa), defined as ISUP GG [greater-than or equal to]2 cancer or [greater-than or equal to]30% positive systematic cores (out of the total number of systematic cores).

Outcome measures

The primary outcome was the detection rate of csPCa in the MRI screening pathway (PSA, PHI, and MRI) compared with the standard screening pathway (PSA and PHI; [Figure 1]). MRI prostate was applied only to men with 4.0-50.0 ng ml-1. The PCa, csPCa, or ISUP GG [greater-than or equal to]2 PCa diagnosed only on MRI-guided-targeted biopsy (but not on systematic biopsies in the standard pathway) was regarded as the additional cancers through MRI pathway.

Secondary outcomes included any grade PCa, ISUP GG [greater-than or equal to]2 PCa, the number of MRI scans needed to detect one extra csPCa, and the number of patients with sepsis after prostatic biopsy. Sepsis was defined according to Sequential (sepsis related) Organ Failure Assessment score of 2 or above in the Sepsis-3 definition.[13]

Statistical analyses

Baseline characteristics of the cohort were compared between men with PSA [greater-than or equal to]4.0 ng ml-1 and PSA <4.0 ng ml-1, using the Chi-square test for categorical variables and Student's t -test for continuous variables. The number of PCa, ISUP GG [greater-than or equal to]2, and csPCa diagnosed in the MRI pathway versus the standard screening pathway was listed. The number of MRI needed to detect one extra PCa compared to the standard screening pathway was calculated. Statistical analyses were performed with SPSS 26.0 (IBM Corp., Armonk, NY, USA). All tests were 2-sided with a significance level at 0.05. The data analyzed in this study are securely managed by the study team and not available as part of a public database but can be made available in a deidentified fashion upon requested.

Results

Patient characteristics

Between August 2018 and September 2020, a total of 1536 patients consented for prostate cancer screening and provided blood samples for PSA and PHI testing. In total, 1340 (87.2%) patients had negative screening result (PSA <4.0 ng ml-1) and the remaining 196 (12.8%) had positive screening result, i.e ., PSA[greater-than or equal to]4.0 ng ml-1. Baseline characteristics of men with or without positive PSA test are listed in [Table 1].{Table 1}

Compliance to investigation in men with abnormal PSA test

All patients with PSA 4.0-9.9 ng ml-1 had PHI result available. In the current cohort (n = 1536), there were 2 men with PSA >50 ng ml-1 and 194 men with PSA 4.0-50.0 ng ml-1. Both men with PSA >50.0 ng ml-1 (n = 2) were diagnosed with nonmetastatic ISUP GG 5 cT3 PCa.

Among the 194 men with PSA 4.0-50.0 ng ml-1 who were indicated for MRI prostate per protocol, 187 (96.4%) had MRI performed, including 95.9% (94/98) in Group 2 (PSA 4.0-9.9 ng ml-1 and PHI <35), 95.2% (60/63) in Group 3 (PSA 4.0-9.9 ng ml-1 and PHI [greater-than or equal to]35), and 100.0% (33/33) in Group 4 (PSA 10.0-50.0 ng ml-1). The MRI and biopsy findings are listed in [Table 2]. Positive MRI (PI-RADS score [greater-than or equal to]3) was seen in 11.7% (11/94) in Group 2, 40.0% (24/60) in Group 3, and 54.5% (18/33) in Group 4.{Table 2}

Out of the total 107 men indicated for prostate biopsy, 94.4% (n =101) received biopsy, including 2 men with PSA >50.0 ng ml-1 and 99 with PSA 4.0-50.0 ng ml-1. Out of 101 prostate biopsies, there were 41.6% (42/101) with any grade PCa, 33.7% (34/101) csPCa and 23.8% (24/101) ISUP GG [greater-than or equal to]2 PCa. Out of the whole cohort (n = 1536), there were 2.7% (42/1536) PCa, 2.2% (34/1536) csPCa, and 1.6% (24/1536) ISUP GG [greater-than or equal to]2 PCa. In the whole cohort with PSA 4.0-50.0 ng ml-1, 45.4% (89/196) men avoided unnecessary prostate biopsy.

Compared with standard pathway, additional of biparametric MRI (in PSA 4.0-50.0 ng ml-1) increased diagnosis of any grade PCa by 21.2% (number of cases increased from 33 to 40), csPCa by 18.5% (from 27 to 32, McNemar test, P = 0.073), ISUP GG [greater-than or equal to]2 PCa by 22.2% (number of cases increased from 18 to 22, P = 0.134), and ISUP GG [greater-than or equal to]3 PCa by 7.7% (number of cases increased from 13 to 14). In Group 2 (PSA 4.0-9.9 ng ml-1 and PHI <35), doing 94 MRI scans resulted in the additional diagnosis of 2 csPCa and one ISUP GG 2 PCa. In Group 3 (PSA 4.0-9.9 ng ml-1 and PHI[greater-than or equal to]35), adding MRI increased diagnosis of PCa by 22.2% (number of cases increased from 18 to 22), csPCa by 25.0% (number of cases increased from 12 to 15), and ISUP GG [greater-than or equal to]2 PCa by 37.5% (number of cases increased from 8 to 11), and 20 MRI scans were needed to diagnose one additional ISUP GG [greater-than or equal to]2 PCa. Moreover, 60 MRI scans were needed to diagnose one additional ISUP GG [greater-than or equal to]3 PCa in Group 3. However, MRI did not increase the diagnosis of PCa, csPCa or ISUP GG [greater-than or equal to]2 PCa in Group 4 (PSA 10.0-50.0 ng ml-1) compared with the standard screening pathway.

In men with elevated PSA 4.0-10.0 ng ml-1, the additional role of PHI was compared with the MRI-only approach. Prostate biopsies in 33 men with nonsuspicious MRI (PI-RADS 1-2) in Group 3 were performed due to PHI [greater-than or equal to]35 [Table 2], and 6 (18.2%) additional PCa was diagnosed, in which 2 (6.1%) were csPCa. This increased csPCa diagnosis in Group 3 by 15.4%, from 13 (in PI-RADS 3-5) to 15 (PI-RADS 1-5) among 33 biopsies, resulting in 16.5 additional biopsies needed to achieve one additional csPCa diagnosis.

The overall post-biopsy sepsis rate was 3.0% (3/101). In total, 4.4% (3/68) of men with transrectal prostate biopsy developed sepsis and required hospitalization, while no postbiopsy sepsis was observed in the 33 men who underwent transperineal prostate biopsy.

Discussion

This is a study to demonstrate the effectiveness of a screening protocol combining PSA, PHI, and MRI prostate in the detection of csPCa or ISUP GG [greater-than or equal to]2 PCa. We observed that the detection of csPCa and ISUP GG [greater-than or equal to]2 PCa was improved and a significant proportion of biopsies could be reduced by adding PHI and MRI to PSA-based screening.

Our results are in line with the recently published randomized controlled trial which shows an improvement of Gleason score [greater-than or equal to]7 PCa detection from 18% to 21%, after adding MRI prostate to the standard PSA screening pathway, in a population-based prostate cancer screening cohort with more than 12 000 participants in Sweden.[14]

Prostate cancer incidence in Asian is only about one-third of that in Caucasian, and cancer detection rates in different PSA ranges

are also 50% less. Reported Caucasian prostate cancer detection rates were 25%-50% in men with PSA 4.0-10.0 ng ml-1 and >50% in men with PSA10.0-20.0 ng ml-1.[15] In Hong Kong Chinese men, only 15% with PSA 4.0-10.0 ng ml-1 and 20%-30% with PSA 10.0-20.0 ng ml-1 have prostate cancer.[9],[16],[17] Although prostate cancer is the second-most common male cancer in the world, population-based organized prostate cancer screening is not a common health policy in most countries because PSA screening leads to unnecessary prostate biopsy and overdiagnosis of clinically insignificant prostate cancer.[4],[5],[6],[7]

One of the strengths of our study was the high compliance to PHI blood test and prostatic biopsy, which is inversely associated with the prostate cancer mortality.[18],[19] The overall compliance of prostatic biopsy was up to 94.3%, which was much higher than the European cohort (40%-91%).[18] The high biopsy compliance in our cohort may be due to the higher health consciousness of the self-referred participants. In addition, all men of PSA [greater-than or equal to]4.0 ng ml-1 had automatic PHI testing in the same tube of blood, and therefore, all PHI results were available in indicated men. This arrangement avoided the noncompliance of return for the PHI test on another day.

Another strength is, instead of only PSA and MRI, the incorporation of PHI blood test in the screening pathway further stratified subjects into different risk groups. MRI prostate was shown to be more effective in detecting ISUP GG [greater-than or equal to]2 PCa in Group 3 subjects (PSA 4.0-9.9 ng ml-1 and PHI [greater-than or equal to]35) when compared to Group 2 subjects (PSA 4.0-9.9 ng ml-1 and PHI <35), as the number of MRI scans needed to diagnose one additional ISUP GG [greater-than or equal to]2 PCa was 20 and 94, respectively. This questions the use of MRI prostate in all men with PSA 4.0-10.0 ng ml-1, and highlights the value of PHI as an additional risk stratification step before consideration of MRI in a PCa screening program. Furthermore, MRI prostate did not detect any additional prostate cancer in Group 4 (PSA 10.0-50.0 ng ml-1). Therefore, MRI may not be essential for screening subjects who had PSA [greater-than or equal to]10.0 ng ml-1.

Biparametric MRI without contrast is used instead of the classical multiparametric MRI with contrast as evidence showed similar cancer detection,[20] reduced scanning time by 42% (38 to 22 min), and avoidance of contrast complications.[21] This is essential in the setting of population-wide large-scale screening.

The additional cost of PHI was about US$100 per test in our locality, and was only 10%-15% of the cost of a biparametric MRI scan. The PHI test is currently available in a large number of Asian countries and therefore can be easily adopted as part of PCa screening. In addition, there was a safety mechanism in our screening strategy. Men who had a negative MRI (PI-RADS score 1-2) were still referred to have prostatic biopsy if their PSA level was [greater-than or equal to]10.0 ng ml-1 or PHI [greater-than or equal to]35.

This study had several limitations. First, although the cost-effectiveness of the screening strategy of combining PSA and PHI test was shown to be more cost-effective than PSA screening alone in the pre-MRI era,[22] whether an additional MRI prostate to the PSA and PHI combined screening strategy is cost-effective remains unknown in the current era. Cost-effective analysis of this novel screening strategy is needed in the future. Second, selection bias exists as all participants were self-referred to this community-based PCa screening program which means they are more health conscious than the general population. Third, the biopsy technique was changed from the initial transrectal to the subsequent transperineal route as the institute switched to transperineal biopsy for better patient safety. A recent systematic review and meta-analysis suggested that both biopsy techniques have similar diagnostic accuracy, but the transperineal approach can reduce infectious complication rates.[23] Finally, the PCa screening program was not population based. Nevertheless, the percentage of recruited patients from the three regions of Hong Kong (China) was 13.7%, 25.1%, and 61.1% for Hong Kong Island, Kowloon, and New Territories, respectively. This closely resembled the data from the Hong Kong population census on population distribution of 16.1%, 30.1%, and 53.7% in the three regions, respectively.[24]

In conclusion, adding MRI prostate to the combined strategy of PSA and PHI blood tests for prostate cancer screening appears to effectively diagnose csPCa while limiting unnecessary biopsies in men with PSA 4.0-10.0 ng ml-1. The benefit of additional MRI was only observed in PSA 4.0-10.0 ng ml-1, and the number of MRI needed to diagnose one additional ISUP GG [greater-than or equal to]2 PCa was 20 in PHI [greater-than or equal to]35 and 94 in PHI 10.0 ng ml-1, adding MRI to PSA and PHI pathway did not increase the diagnosis of PCa or csPCa. Incorporation of transperineal biopsy could improve the risk-benefit ratio in PCa screening by eliminating sepsis.

Author Contributions

PKFC contributed to conceptualization, data curation, formal analysis, investigation, methodology, and writing the original draft. TYTL contributed to data curation, formal analysis, investigation, methodology, and writing the original draft. CFN contributed to conceptualization, supervision, review, and editing. JYCT contributed to methodology and project administration. CCMC and HYH contributed to data curation and investigation. CH contributed to data curation, project, and administration. MJR contributed to methodology, review, and editing. WCWC contributed to supervision and investigation. SYSW contributed to supervision, review, editing, and project administration. JJYS contributed to conceptualization, methodology, supervision, review, and editing. All authors read and approved the final manuscript.

Competing Interests

All authors declared no competing interests.

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