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Trends of stratified prostate cancer risk in a single Korean province from 2003 to 2021: A multicenter study conducted using regional training hospital data

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Purpose: To identify changes in prostate cancer (PCa) risk-stratification during the last two decades in Korea, where the social perception of PCa was limited due to a relatively low incidence but has recently been triggered by the rapidly increasing incidence of benign prostate hyperplasia.

Materials and Methods: Retrospective data of patients who had received a diagnosis of PCa in a single Korean province (Daegu-Gyeongsangbuk) at all seven training hospitals in the years 2003, 2007, 2011, 2015, 2019, and 2021 were subjected to analysis. Changes in PCa risk-stratification were investigated with respect to serum prostate-specific antigen (PSA), Gleason score (GS), and clinical stage.

Results: Of the 3,393 study subjects that received a diagnosis of PCa, 64.1% had high-risk disease, 23.0% intermediate, and 12.9% low-risk disease. The proportion diagnosed with high-risk disease was 54.8% in 2003, 30.6% in 2019, but then increased to 35.1% in 2021. The proportion of patients with high PSA (>20 ng/mL) steadily decreased from 59.4% in 2003 to 29.6% in 2021, whereas the proportion with a high GS (>8) increased from 32.8% in 2011 to 34.0% in 2021, and the proportion with advanced stage disease (over cT2c) increased from 26.5% in 2011 to 37.1% in 2021.

Conclusions: In this retrospective study, conducted in a single Korean province, high-risk PCa accounted for the largest proportion of newly registered Korean PCa patients during the last two decades and increased in the early 2020s. This outcome supports the adoption of nationwide PSA screening, regardless of current Western guidelines.

Keywords: Prostate-specific antigen; Prostatic neoplasms; Risk assessment

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INTRODUCTION

The benefits of prostate-specific antigen (PSA) based prostate cancer (PCa) screening policies have remained controversial since 2012 [1] when the US Preventive Study Task Force (USPSTF) acted to discourage PSA testing due to conflicting evidence on the effects of public screening on long-term survival [2,3] and the risks of over-diagnosis and treatment of 'insignificant' PCa [4]. Nevertheless, serum PSA testing continues to play a pivotal role in the early detection of PCa, given that the majority of individuals with early-stage PCa do not manifest specific symptoms other than ambiguous male lower urinary tract symptoms (LUTS), which frequently are attributed to concomitant benign prostate hyperplasia (BPH).

During the last two decades, the crude incidence of PCa in Korea has increased 10-fold (from 3.1 per 100,000 population in 1999 to 32.7 per 100,000 population in 2019) and mortalities have increased 4-fold (from 0.9 per 100,000 population in 1999 to 4.0 per 100,000 population in 2019), despite limited social awareness of the disease. Indeed, in a public survey performed in 2019, only 9.7% of Korean males aged over 40 years were aware of PSA testing, and 83.3% had never been screened [5]. In this age group, the nationwide annual rate of PSA testing during the period 2006 to 2016 has remained at only 2% to 7%, which is less than a quarter of that reported in the US during the same period [6]. Furthermore, a report on the lack of cost-effectiveness of PSA-based screening based on Korean national insurance data published in 2014 [7] reinforced the prevailing assumption of low-risk dominant PCa in Korea, because of several US data-based articles identically reported a significant downward shift of risk during the two decades following the approval of PSA test as a monitoring tool for PCa in 1986 [8,9].

Though countrywide PCa risk-stratification has not been explored, we investigated the topic using data from Daegu-Gyeongsangbuk province, which accounts for ≤12% of the Korean population. The purpose of this study was to reflect on and document changes in PCa risk over the past two decades in Korea, where social perceptions of PCa have recently been triggered by a rapid increase in the incidence of BPH among the elderly.

MATERIALS AND METHODS

1. Data acquisition and study design

Retrospective data of patients that received a diagnosis of PCa in a single Korean province (Daegu-Gyeongsangbuk) at any of the 7 training hospitals in the province during 2003, 2007, 2011, 2015, 2019, and 2021 were subjected to analysis after obtaining Institutional Review Board approval (approval no. YUMC-2022-04-013). The written informed consent was waived by the board due to the retrospective design of the study. The inclusion criterion was histologically confirmed PCa diagnosed by prostate biopsy. Variables used for PCa risk stratification were; age, initial PSA value before biopsy, the first and second Gleason scores (GS, including Gleason grade groups), clinical stage based on digital rectal examination, and a radiologic evaluation (computed tomography, magnetic resonance imaging (MRI), and bone scan all of which are fully covered by national medical insurance system), and other variables, which included positive core number and percentages of tumor in biopsy cores. No specific exclusion criteria were applied regardless of the surgical approach used (transrectal or transperineal), biopsy method (ultrasonic- or MRI fusion-based biopsy), or the number of biopsy cores. The final pathologic stages of patients managed by radical prostatectomy were not investigated.

2. Study design and statistical analysis

Changes in PCa risk stratification were investigated for serum PSA, GS, and clinical stages. PCa risk stratifications were categorized according to contemporary guidelines, as follows; high-risk (PSA≥20 ng/mL, or GS≥8, or clinical stage≥T2c), intermediate-risk, and low-risk (PSA<10 ng/mL, and GS 6, and clinical-stage≤T2a). The Student's t-test was used to compare continuous variables and the chi-squared test to compare binary and categorical variables. The trend by year was tested using Linear-by-linear association. The analysis was performed using SPSS Statistics ver. 27.0 (IBM Corp.). Statistical significance was accepted for p-values <0.05.

RESULTS

1. Characteristics of the study subjects

The data of the 3,393 PCa patients newly diagnosed in Daegu-Gyeongsangbuk province that covered almost two decades sampled by 6 times were collected. The total number of biopsy cores significantly increased from 5.2±2.1 in 2003 to 11.7±1.5 in 2021 (p<0.001). The cases with MRI fusion biopsy also increased up to 18.1% in 2021, in comparison with 8.3% in 2019 (p<0.001). However, the biopsy core number were maintained similarly since 2015, when 11.8±1.1 cores were obtained (p=0.467). Transrectal 12-core biopsy occupies 84.2% of cases (n=2,817), and MRI fusion biopsy was performed in 9.1% of cases (n=297).

The number of PCa patients included increased from 49 in 2003 to 1,064 in 2021. Of the study subjects, 64.1% (n=2,174)

had high-risk disease, 23.0% (n=790) intermediate-risk disease, and 12.9% (n=439) low-risk disease. The mean age at pathologic diagnosis was maintained at 71 years across the study years, but risk-stratification variables changed significantly. Though the mean initial PSA level gradually decreased from 383.0 ng/mL in 2003, it remained high at 64.1 ng/mL in 2021 (Table 1).

2. PCa risk stratification trends in the study area

The percentage of patients in the high-risk group was 54.8% in 2003, decreased progressively to 30.6% in 2019, but then increased to 35.1% in 2021 (Fig. 1). The percentage of patients with a high PSA (≥20 ng/mL) consistently decreased from 59.4% in 2003 to 29.6% in 2021 (Fig. 2A), and the percentage with a high GS (≥8) increased from 32.8% in 2011 to 34.0% in 2021, and the percentage with a high stage (over cT2c) increased from 26.5% in 2011 to 37.1% in 2021 (Fig. 2B, C).

For those in the high-risk subgroup, the percentage with a high PSA gradually decreased across the study period (Fig. 3A, p<0.001). The percentage with a high GS was maintained (Fig. 3B, p=0.144), but the percentage with a high clinical stage increased (Fig. 3C, p<0.001). A similar recent increase in the clinical stage was also observed in the intermediate-risk subgroup (Fig. 3C).

DISCUSSION

Unlike the US or Europe, which have a long history of clinical application, ready access to PSA testing, and greater social awareness of PCa than any Asian country, the incidence of PCa in the majority of Asian countries has soared recently. As in other Asian countries [10], the incidence of PCa in Korea has increased rapidly over the last decade. Since 2002, when PCa was first reported to be the fifth most common male malignant disease, the incidence of PCa has continued and reached the fourth position in 2016. In the most recent report (2019), PCa was the third most prevalent cancer among Korean males and the second most common cancer among men over 65 [11]. One of the unique differences between PCa in Asia and the West is that its increasing incidence in Asia appears to be driven dominantly by the elderly and super-elderly (≥75 years). In Japan, where PCa became the most common male cancer in 2018, about two-thirds of registered patients were older than 75 years [12]. From the Korean data in the same year, 90% of PCa patients registered in the national database were ≥60 years (90.4%, 13,442 out of 14,856 registered PCa), and around a third were ≥75 years (35.4%, 5,259 out of 14,856 registered PCa). In contrast, in the US, the percentage of men aged ≥75 years among PCa patients diminished from ≤50% to 20% between 1975 and 2016 [4]. Because the increasing prevalence of PCa in Korea is driven by the elderly population, who tend to have concomitant LUTS/BPH and thus are more likely to undergo PSA testing than their younger counterparts, the incidence of PCa is projected to increase in parallel with societal aging.

The ultimate aim of a population-based screening strategy is to promote cancer-specific survival. From this perspective, the USPSTF recommended against PSA screening of the general population mainly based on western-based randomized controlled trials performed between the late 1990s and early 2000s. Although the USPSTF modified its original prohibitive recommendations in 2018 [13], opening slots for PSA screening for the explained individuals aged 55 to 69 years, the macroscopic consequence of accepting a specific screening strategy could be quite different in each country. How contemporary western guidelines, based on USPSTF recommendations on PSA screening, apply in Korea remains vague, given a low incidence of PSA testing and the high proportion of elderly among newly diagnosed PCa cases.

The outcomes of our study provide positive evidence supporting the need for PSA screening in Korea because high-risk patients were found to account for one-third of patients with newly diagnosed PCa. Given that the PSA testing of men with a suspected malignancy has been subject to medical insurance reimbursement in Korea since 2007, 15 years since then should have been enough to realize the stage shift as observed in the US. Cooperberg et al. [9] categorized 6,260 men with complete clinical information diagnosed with PCa from 1989 to 2002 into low, intermediate, or high-risk groups using CaPSURE (Cancer of the Prostate Strategic Urological Research Endeavor) data. They reported the proportion of high-risk cases decreased from 40.9% in 1989 to 14.8% in 2002 and that the proportion of low-risk cases increased from 31.2% in 1989 to 47.7% in 2002. Notably, the proportion of patients with an initial PSA of >20 ng/mL decreased from 27% to 8.1% during the study period. However, this downward shift coincided precisely with a dramatic increase in PSA testing.

In the US, PSA testing was first used for population screening in 1988 [14], and in 1992, around 25% of men aged ≥50 years had undergone at least one test [15]. PSA screening then continued to increase after the Food and Drug Administration approved the PSA test for screening purposes in 1992. In an annual population-based survey of adults conducted by the US Centers for Disease Control and Prevention in 2001, 75% of men aged ≥50 years had undergone

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Table 1. Study subject characteristics

Characteristic	Year						p-value
	2003	2007	2011	2015	2019	2021	
No. of patients	49	183	460	560	1,077	1,064	
Age (y)	71.0±7.4	71.1±8.2	71.1±7.8	71.3±8.0	71.4±7.9	71.5±8.1	0.967
≤54	1 (2.0)	3 (1.6)	10 (2.2)	7 (1.3)	19 (1.8)	23 (2.2)	0.984
55–69	18 (36.7)	69 (37.7)	187 (40.7)	224 (40.0)	434 (40.3)	421 (39.6)	
≥70	30 (61.2)	111 (60.7)	263 (57.2)	329 (58.8)	624 (57.9)	620 (58.3)	
PSA value (ng/mL)	383.0±1,533.7	236.3±751.2	104.2±581.8	68.8±288.8	82.0±421.1	64.1±247.4	<0.001*
<10	11 (22.4)	42 (23.0)	207 (45.0)	277 (49.5)	547 (50.8)	530 (49.8)	<0.001*
10–19	8 (16.3)	38 (20.8)	86 (18.7)	96 (17.1)	219 (20.3)	227 (21.3)	
≥20	30 (61.2)	101 (55.2)	167 (36.3)	184 (32.9)	309 (28.7)	306 (28.8)	
Prostate volume (g)	53.5±28.7	43±21.8	38.2±20.7	39.8±25.6	38.9±22.5	41.7±40.2	0.013*
Gleason score							
6 (GGG 1)	10 (20.4)	22 (12.0)	114 (24.8)	130 (23.2)	256 (23.8)	254 (23.9)	<0.001*
3+4 (GGG 2)	9 (18.4)	22 (12.0)	65 (14.1)	100 (17.9)	173 (16.1)	167 (15.7)	
4+3 (GGG 3)	9 (18.4)	25 (13.7)	61 (13.3)	74 (13.2)	142 (13.2)	120 (11.3)	
8 (GGG 4)	12 (24.5)	58 (31.7)	121 (26.3)	144 (25.7)	311 (28.9)	375 (35.2)	
9, 10 (GGG 5)	9 (18.4)	56 (30.6)	99 (21.5)	112 (20.0)	195 (18.1)	148 (13.9)	
Total biopsy core number	5.2±2.1	9.7±3.8	11.3±2.0	11.8±1.1	11.7±1.4	11.7±1.5	<0.001*
Case with MRI fusion biopsy (%)	6 (12.2)	2 (1.1)	2 (0.4)	6 (1.1)	89 (8.3)	192 (18.0)	<0.001*
Clinical stage							
≤T2a	3 (6.1)	21 (11.5)	112 (24.3)	151 (27.0)	235 (21.8)	158 (14.8)	<0.001*
T2b	7 (14.3)	50 (27.3)	129 (28.0)	138 (24.6)	352 (32.7)	354 (33.3)	
≥T2c	16 (32.7)	68 (37.2)	136 (29.6)	234 (41.8)	405 (37.6)	443 (41.6)	
Metastatic disease	9 (18.4)	17 (9.3)	23 (5.0)	33 (5.9)	55 (5.1)	61 (5.7)	<0.001*

Values are presented as mean±standard deviation or number (%).
PSA, prostate-specific antigen; GGG, Gleason grade group; MRI, magnetic resonance imaging.
*Statistically significant p<0.05.

PSA testing, and 54% had undergone repeat testing [16]. In the 2010s, despite the negative recommendation from USPSTF, this high rate of PSA testing appears to have been maintained in the US, except among the elderly. A National Health Interview Survey during the period 2005–2015 [17] showed that the proportion of men in the US aged >55 years who had undergone a PSA test was slightly lower than the maximum estimate of 43.1% in 2008 but had been since maintained at >30% (32.8% in 2013 and 33.8% in 2015). Following the first prohibitive recommendations for PSA screening issued by the USPSTF in 2008 for men aged over 75 [18,19], a clear diminishing trend was observed among men aged >70 (from 51.1% in 2008 to 36.4% in 2015). On the other hand, more recent data (2016–2019) showed a 12.5% increase in PSA testing in men aged 40 to 89 years in the US [20]. Similarly, in a cross-sectional study by the US Veterans Health Administration (2009–2018), the incidence of PSA testing among men aged 55–69 years increased slightly from 41% to 43.5% [21]. In 2018, a study based on US data reported a screening prevalence of 43% among veterans and 40% among non-veterans aged between 55 and 69 years [22].

The present study is limited by the relatively small number of patients residing in Daegu-Gyeongsangbuk province and the use of training hospital data, and thus, we cannot claim that our findings precisely represent nationwide PCa risk-stratifications. However, annual cancer registry data demonstrate similar epidemiologic characteristics, particularly regarding the incidences of PCa in Daegu-Gyeongsangbuk province (34.2 per 100,000 population in Daegu city and 32.0 per 100,000 population in Gyeongsangbuk province) and 34.3 per 100,000 population nationwide [11]. In addition, the nationwide medical insurance reimbursement system in Korea covers most malignant diseases, including PCa, which means that the financial impacts of detection are similar regardless of the residential area. The change in the standard protocol for prostate biopsy methods across the last two decades in terms of biopsy core number, approach routes to the prostate, and the implementation of MRI fusion biopsy may impact the detection rate of high-risk diseases. However, the best majority of cases were performed via conventional 12-core transrectal ultrasound guidance, and the biopsy core number was maintained at about 12 since 2011 (Table 1). Though the cases with MRI fusion biopsy increased significantly from the recent data based on the revision of guidelines, our intention from this observational series was to illustrate the trend of PCa risk stratification especially focused on the recent change, not to compare the detectability between different methodologies. As shown in Fig. 2B, the GS which was the most objective indicator for high-risk disease than other variables remained unchanged for the recent decade.

Taking these findings into account, we surmise that the

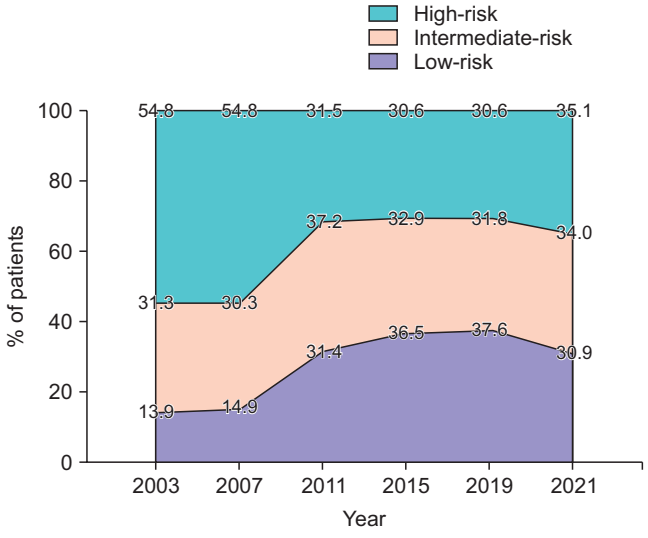

Fig. 1. Changes in prostate cancer risk-stratification during 2003–2021 based on the data of pathologically confirmed patients at seven academic hospitals in Daegu-Gyeongsangbuk province, Korea.

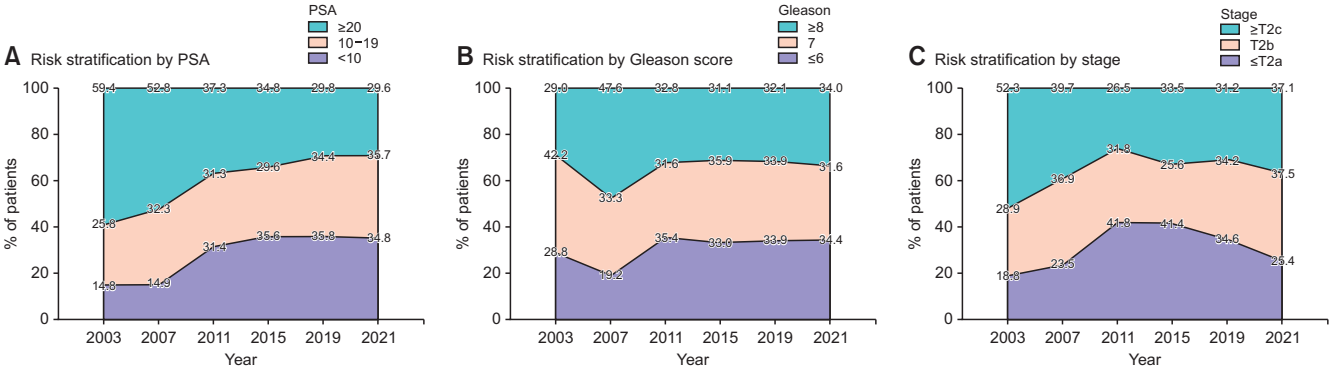

Fig. 2. Changes in prostate cancer risk-stratification during 2003–2021 in Daegu-Gyeongsangbuk province as determined by serum prostate-specific antigen (PSA) levels (A), Gleason scores (B), and clinical stages (C).

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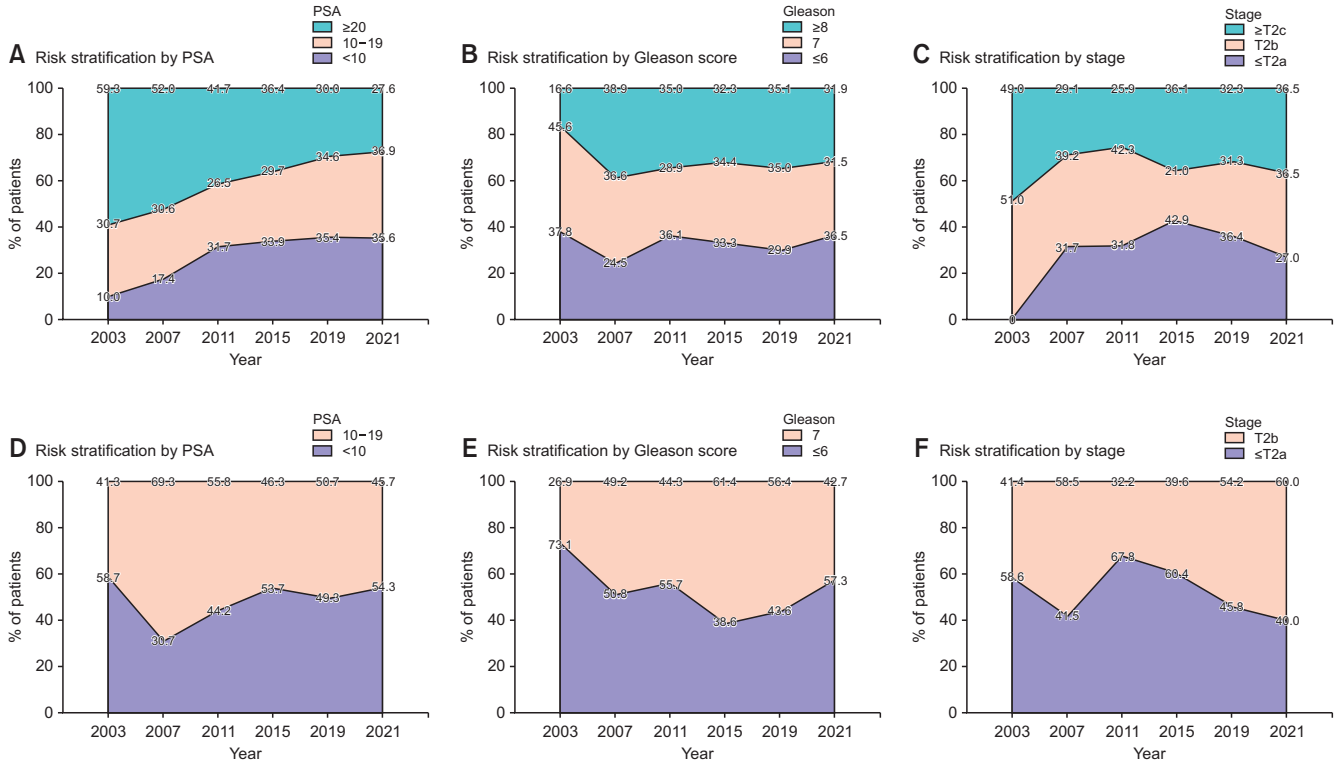

Fig. 3. Changes in prostate cancer risk-stratification during 2003–2021 in Daegu-Gyeongsangbuk province in the high-risk (A–C) and intermediate-risk (D–F) subgroups as determined by serum prostate-specific antigen (PSA) levels, Gleason scores, and clinical stages.

substantially lower rate of PSA testing in Korea than in the US is a fundamental cause of the lack of a downward shift in PCa risk-stratification in Korea over a similar period [9]. From the most recently available national-wide data in 2016, the incidence of PSA testing in men aged ≥40 years was 7.28% in Korea. Among the inhabitants of this study (Daegu-Gyeongsangbuk province), PSA testing was performed in 6.1% of men aged in their 50's [6]. In contrast to the prevailing public belief of a reduction in the incidence of high-risk PCa as reported in the US in the early 2000s, the high-risk disease still accounts for the greatest proportion of newly registered Korean PCa patients, and this proportion was greater in the early 2020s than in the 2010s. Considering that elderly men tend to present with higher grades and stages [23,24], social aging in Korea may negatively affect the epidemiological characteristics of PCa. Yet, in the absence of public screening in Korea, PSA testing continues to be performed opportunistically and to be driven dominantly by the private sector during routine check-ups and BPH patients. Our findings, therefore, suggest a public need for PSA testing, especially for men unlikely to undergo personal medical check-ups or without BPH symptoms.

CONCLUSIONS

In this retrospective study conducted in a single Korean province by tertiary hospitals, high-risk PCa accounted for the largest proportion of newly registered Korean PCa patients over the past two decades and increased in the early 2020s. Considering the limited social perception and unequal opportunities for PSA testing in Korea, our findings indicate that the adoption of public PSA screening would substantially increase the detection of men at risk of significant PCa in a background of recent increased incidence, in contrast to the contemporary western-based prohibitive guidelines.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Young Hwii Ko and Byung Hoon Kim. Data acquisition: Young Hwii Ko, Byung Hoon Kim, Se Yun Kwon, Hyun Jin Jung, Yoon Soo Hah, Yeon-Joo Kim, Hyun Tae Kim, Jun Nyung Lee, and Tae-Hwan Kim. Statistical analysis: Young Hwii Ko and Jeong Hyun Kim. Data analysis and interpretation: Byung Hoon Kim. Drafting of the manuscript: Se Yun Kwon. Critical revision of the manuscript: Jeong Hyun Kim. Obtaining funding: Young Hwii Ko. Administrative, technical, or material support: Yoon Soo Hah. Supervision: Young Hwii Ko and Byung Hoon Kim. Approval of the final manuscript: all authors.

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