J Korean Med Sci. 2026 Apr 13;41(14):e10
https://doi.org/10.3346/jkms.2026.41.e10
eISSN 1598-6357·pISSN 1011-8934

JKMS

Original Article
Oncology & Hematology

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Incidence of High-Risk Prostate Cancer in Korea: Insights From Real-World Data Between 2010 and 2020

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OPEN ACCESS

Received: Mar 31, 2025
Accepted: Jul 15, 2025
Published online: Oct 29, 2025

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Funding
This study was supported by a grant from the National Research Foundation of Korea (NRF) funded by the Korean government (MSIT) (No.2022R1A2C1009074) and the Korea Health Industry Development Institute (RS-2023-00262969).

ABSTRACT

Background: This study aims to report the nationwide risk stratification of prostate cancer (PCa) over the past decade—an analysis that has not been previously conducted, as such data are not available through the medical insurance-based big data registry of South Korea.
Methods: Nationwide data on the clinicopathologic variables of PCa at the time of diagnosis through biopsy, prostate-specific antigen (PSA) levels, clinical stage, Gleason grade, and residential area of the patient were obtained from 51 general hospitals (with ≥ 200 beds) across South Korea in 2010, 2012, 2014, 2016, 2018, and 2020. The risk criteria were based on universal guidelines defined in the 2010s, with high risk defined as PSA levels > 20 ng/mL, clinical stage ≥ cT3a, and Gleason group (GG) ≥ 4; low risk was defined as PSA levels < 10 ng/mL, clinical stage ≤ cT2a, and GG < 1.
Results: Data from 27,075 cases, representing 37.9% of the 71,403 patients registered in the National Cancer Statistics during the study period, were obtained from 51 hospitals. High-risk PCa (50.6%) was the most prevalent disease during the study period, while the proportion of low-risk diseases, including potential low-risk cases, decreased from 11.4% in 2010 to 7.6% in 2020. High-risk PCa was most prevalent in 9 of the 17 administrative regions, with 55.4% of high-risk cancer cases originating in rural areas compared to 47.7% from urban areas ($P < 0.001$).
Conclusion: Approximately 50% of the patients with PCa detected in South Korea in the 2010s had high-risk disease, which was a consistent nationwide. The higher prevalence of low-risk disease among residents of the capital metropolitan area, compared to the higher frequency of high-risk disease among rural residents, suggests disparities in access to early PCa detection and diagnosis.

Keywords: Prostate Cancer; Screening; Prostate-Specific Antigen

INTRODUCTION

Owing to the absence of distinctive clinical manifestations in non-metastatic prostate cancer (PCa), apart from lower urinary tract symptoms similar to those observed in benign prostatic hyperplasia, the results of prostate-specific antigen (PSA) assays are critically important for the early identification of PCa. PSA testing is an efficient screening procedure; however, most

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Disclosure
The authors have no potential conflicts of interest to disclose.

Author Contributions
Conceptualization: Ko YH. Data curation: Ko YH. Formal analysis: Kim SW. Funding acquisition: Ko YH. Investigation: Ko YH. Methodology: Ko YH, Son NH. Project administration: Ko YH. Resources: Ko YH. Software: Kim SW, Son NH. Supervision: Ko YH. Validation: Kim SW, Ko YH. Visualization: Ko YH. Writing - original draft: Ko YH. Writing - review & editing: Ko YH, Son NH, Kim SW.

clinical guidelines released in the early 2010s curtailed PSA screening recommendations.[1-4] These prohibitive recommendations primarily stemmed from the absence of robust and consistent evidence substantiating the clinical benefits of PSA screening within the general population, resulting from concerns about overdiagnosis and overtreatment.[2,5] Limited awareness and access to PSA testing may contribute to a higher prevalence of high-risk and advanced-stage PCa at diagnosis.

In contrast, the widespread adoption of PSA screening in the US, following its endorsement in 1986, led to a marked shift in risk stratification in the early 2000s. The proportion of high-risk PCa decreased from 40.9% in 1989 to 14.8% in 2002, while PSA the proportion of low-risk disease increased from 31.2% to 47.7%.[6] During this period, the frequency of PSA testing was 56% in men aged ≥ 50 years.[7-9] The persistent trend of high-risk cases appears to be consistent with data from the Surveillance, Epidemiology, and End Results (SEERs) registrations between 2010 and 2015; the proportions of low-risk, intermediate-risk, and high-risk PCa were 29.7%, 47.8%, and 22.5%, respectively.[10]

In South Korea, where the proportion of men aged 40 and over undergoing PSA testing remained below 10% throughout the 2010s, the distribution of PCa risk stratification remains largely unknown.[11] Given the considerable proportion of high-risk PCa cases, a reassessment of the current screening strategy is warranted, in accordance with the updated recommendations from the 2020s that highlight the role of initial PSA testing in decision-making.[12,13] The insurance-based registration system in South Korea does not include key information on PSA levels, stage, and grade for risk classification of PCa; hence, we investigated the nationwide actual clinical pathological characteristics at the time of diagnosis from 2010 to 2020.

METHODS

Selection of patients and data acquisition

A comprehensive nationwide database collected data on the clinicopathologic characteristics of patients with PCa at the time of prostate biopsy in 2010, 2012, 2014, 2016, 2018, and 2020. From this database, we screened for data from hospitals across South Korea with urology departments having ≥ 200 beds. Data collection for this study was performed between February 2022 and September 2024. The cohort of patients included in this study met the criteria for histologically verified PCa, regardless of the biopsy technique employed, which included transrectal, transperineal, and magnetic resonance imaging (MRI) fusion methodologies, as outlined in institutional protocols during the designated study years.

To stratify the risk associated with PCa, pertinent variables, such as serum PSA levels before biopsy, clinical staging, and International Society of Urological Pathology (ISUP) grade group score, were systematically collected. To ascertain clinical staging, patients underwent comprehensive radiological assessments, including computed tomography (CT), MRI, and bone scintigraphy, all financed by the national health insurance of South Korea, following their registration in the database as patients with PCa. Risk classification adhered to the criteria set by the National Comprehensive Cancer Network guidelines, categorizing high-risk as any one of the following: PSA levels ≥ 20 ng/mL, clinical stage ≥ cT3a, and ISUP grade group ≥ 4. Conversely, low-risk was defined as PSA levels < 10 ng/mL, clinical stage ≤ cT2a, and ISUP grade group 1. Nonetheless, patients were designated as potentially low risk

if they fulfilled at least one of the three low-risk criteria, taking into account the presence of missing data. The remaining patients were classified as having intermediate risk according to the established clinical guidelines.

In addition to clinical data on PCa, the patient's age and place of residence at the time of biopsy—without any other personal identifiers—were collected to reflect minimally reflect socioeconomic status. Residence area included information on the current place of residence among the 17 nationwide administrative districts, and information on whether the residence area was classified as rural or urban (in South Korea, each administrative district is divided into "eup/myeon" and "dong" areas).

Statistical analysis

The Student's *t*-test was used to evaluate continuous variables, while the χ^2 test was used to compare binary and categorical variables. Trends in the alteration of PCa risk with advancing age were assessed using a linear-by-linear association analysis. Univariate analysis was performed using a logistic regression model that was concurrently used to calibrate the multivariate variables. Statistical analyses were performed using SPSS Statistics ver. 27.0 (IBM Corp., Armonk, NY, USA). Statistical significance was defined as $P < 0.001$.

Ethics statement

Institutional Review Board (IRB) of Yeungnam University Hospital approval was obtained, and the requirement for informed consent was waived as no personal identifiers were collected (IRB No. YUMC 2022-09-030.

RESULTS

Representativeness of acquired data compared to the nationally registered data

During the study period, data from 27,075 patients with PCa were pooled from 51 hospitals, representing 37.9% of the 71,403 patients registered with the National Cancer Statistics between 2010 and 2020. The number of patients examined and the percentage of registered patients increased each year, reaching 29.4% (2,407 of 8,178) in 2010, 34.8% (3,288 of 9,434) in 2012, 38.6% (3,860 of 9,991) in 2014, 36.1% (4,339 of 12,002) in 2016, 38.6% (7,395 of 14,983) in 2018, and 43.5% (7,395 of 16,815) in 2020.

The age (mean ± standard deviation) of the investigated patients was 69.4 ± 10.3 years; 94% had undergone a first biopsy, and 4.9% had undergone a second biopsy. The level of PSA at the time of biopsy was 20.5 ± 30.5 ng/mL, with 200 ng/mL as an outlier. The total number of cores obtained during biopsy was 11.8 ± 2.3 m, and the number of positive cores was 5.1 ± 3.6, with 90.4% of all patients undergoing CT or MRI and 84.5% undergoing bone scans. During the investigation period (February 2022–September 2024), 1,836 participants (6.8%) of the overall study cohort, died, of which 491 (26.7%) deaths were attributed to PCa.

Temporal and regional variation in the risk classification criteria of patients investigated

High-risk disease was prevalent (50.6%) during the study period (**Fig. 1**), while the proportion of the low-risk group, including potentially low-risk patients, decreased from 11.4% in 2010 to 7.6% in 2020 ($P < 0.001$). When all three criteria indicated low-risk PCa, the proportion

https://doi.org/10.3346/jkms.2026.41.e10

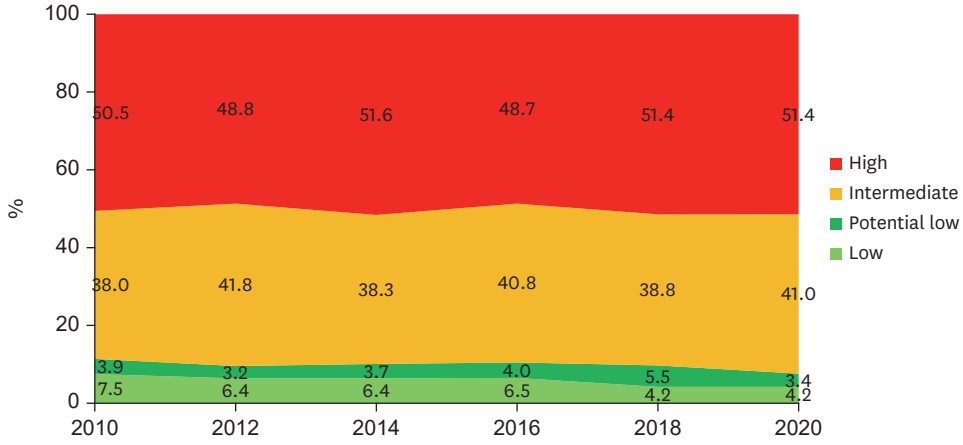


Fig. 1. Changes in the distribution of prostate cancer risk-stratification among investigated patients from 2010 to 2020.

of such cases decreased significantly from 7.5% in 2010 to 4.2% in 2020 ($P < 0.001$). When stratified by the 17 administrative districts, high-risk PCa was the most prevalent category in 9 districts, showing the highest proportion overall ($P < 0.001$) (**Fig. 2**). In the metropolitan areas of Seoul, Incheon, and Gyeonggi-do, characterized by the highest population density in South Korea and a relatively young demographic, the incidence of low-risk cancers was 13.6%, 14.8%, and 14.5%, respectively. In the other areas, the prevalence of low-risk cancers was < 10%, with the exceptions of Jeollabuk-do (13.6%) and Sejong City (11.1%).

When residential areas were categorized as rural or urban, the proportion of high-risk PCa was significantly higher in rural (55.4%) compared to urban areas (47.7%) (**Fig. 3**) ($P < 0.001$). The average age in the two regions was 71.2 ± 7.8 years and 69.6 ± 8.2 years, respectively, with a statistically significant difference observed the rural area ($P < 0.001$).

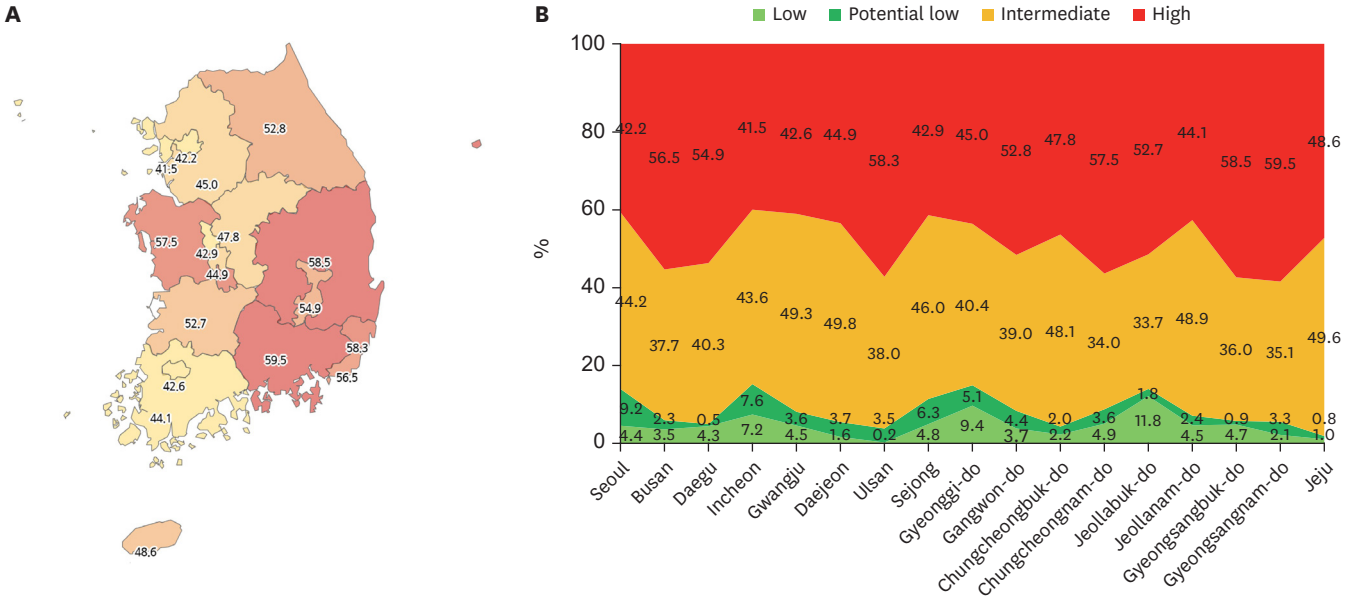


Fig. 2. Map indicating the regional distribution of the proportion of high-risk prostate cancer according to the 17 administrative regions in South Korea (**A**) and graph of the overall risk distribution (**B**).

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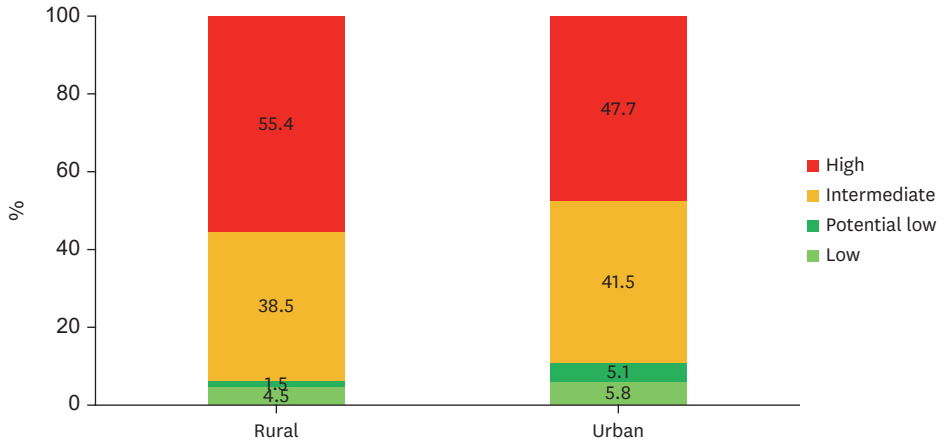


Fig. 3. Comparison of the proportion of prostate cancer risk stratification in rural and urban areas based on the population density of the location of residence (officially based on a population density of 50,000).

DISCUSSION

Although PCa is the most prevalent cancer among men worldwide and the second leading cause of cancer-related deaths in men,[14] it has been considered a low-incidence disease in Asian countries. During the 2010s, however, the incidence of PCa increased significantly in Asian countries. In China, the age-standardized incidence rate increased by 95.2% from 1990 to 2019, highlighting a concerning trend.[15] Similarly, Japan experienced a rapid increase in incidence, with rates increasing approximately 102% in certain regions.[16] Between 2002 and 2022, the age-standardized incidence rate of PCa in South Korea increased from 8.6 to 84.2 per 100,000 men, and the age-standardized mortality rate increased from 2.7 to an estimated 28.4 per 100,000, indicating a nearly 10-fold increase in both incidence and mortality over two decades. Nevertheless, PSA testing has not been widely used in Asia,[17] except in Japan, based on medical guidelines in the early 2010s. These guidelines were influenced by the U.S.-based PLCO trial, which failed to demonstrate a significant reduction in PCa mortality through PSA-based screening.[18] As a result, the emphasis shifted toward individualized screening based on shared decision-making, rather than population-wide screening. In this context, it is worth noting that this study, which examined the risk stratification of PCa based on real-world data in South Korea, found that the situation was contrary to pre-existing expectations that expected the results to be similar to those of Western studies.

The results revealed by this study are as follows: First, contrary to the low-risk-dominated PCa risk structure expected based on Western investigations in the early 2000s, high-risk disease was the most common type of PCa, accounting for approximately half of the PCa patients diagnosed in Korea during the 2010s. High-risk and very high-risk diseases account for a significant portion of PCa-specific mortality despite representing a smaller fraction of diagnoses. Based on the results from the SEER database between 2004 and 2015, although high-risk (18.1% among total PCa diagnoses during the study year) and very high-risk (3.0%) diseases accounted for only 21.1% of PCa diagnoses, they accounted for 65.3% of 10-year PCa-specific mortality.[19] Nevertheless, the proportion of high-risk diseases has remained stable since 2000, with no significant downward trend in risk levels among high-risk patients. A US research study examined trends in PCa incidence (number of cases per 100,000 population) using 17 registries from the SEER program from 2000 to 2020, recruiting 1,098,349 patients.[20] When categorizing it into the periods of 2000–2006, 2007–

https://doi.org/10.3346/jkms.2026.41.e10

2013, and 2014–2020, the incidence of the local stage occupies the highest proportion in all three periods (182.3, 147.9, and 139.7, respectively). Although the incidence of advanced stage was slightly increased in the most recent period (10.7%, 10.2%, and 13.9%, respectively), the incidence of regional stage, defined as node metastasis, consistently decreased (23.7%, 20.8%, and 19.5%, respectively). From 2004 to 2014, there was a notable increase (from 21.19% to 26.05%) in the proportion of men diagnosed with high-risk PCa. This trend was primarily driven by an increase in high-grade diseases, such as Gleason grades 7–10.[21] During a similar period, across four large European centers, the high-risk cases increased from 10% in 2000 to 30% in 2015.[22] Given that PCa has been a significant cause of cancer deaths among men in the US and European countries since the 1970s, a particularly noteworthy finding of this study is that the number of cases of high-risk disease in South Korea—where awareness and implementation of PSA testing is lower than in these countries—is about twice as high as in these countries.

Although high-risk cancers are prevalent in South Korea, PCa has a relatively long survival period, and recent advances in drug therapy and new treatment strategies have significantly improved survival rates in these patients. Therefore, even if PSA testing becomes more common, demonstrating a statistically significant reduction in cancer-specific mortality rates remains challenging. In this context, a key implication of this study is that PSA screening may help ensure more equitable health outcomes—particularly for individuals unlikely to undergo testing without opportunistic encounters, but are at risk of developing high-risk PCa. Information on PSA tests remains unevenly distributed and far from universal; in a relatively recent survey, fewer than 10% of non-medical individuals recognized PSA as a screening test for PCa.[23] PCa screening in South Korea typically occurs only when PSA testing is incidentally included in a patient's health check-up or during a specialist consultation for lower urinary tract symptoms, its detection disproportionately favors individuals with higher education and income levels—unlike trends observed in other major cancers in men.[24] These characteristics lead to disparities in medical literacy and access to healthcare, which, in turn, likely result in differences in opportunities for PCa screening based on areas where people reside. When the number of repeated PSA tests was investigated for each of the 17 administrative districts in South Korea between 2008 and 2016, it was found that only residents of Seoul underwent more than 3 tests. The frequency of PCa was higher in rural areas, where there was a higher proportion of older individuals. However, the frequency of PSA tests was paradoxically higher among residents of large cities.[25] The results of this study also reflected these differences. The proportion of low-risk cancers among residents of the 3 administrative districts in the Capital Area (Seoul, Incheon, and Gyeonggi-do Province), which has the highest population density in South Korea, was higher than that among residents in other regions. In contrast, the proportion of high-risk cancers among residents in rural areas was higher, strongly suggesting that the lack of uniformity in of PSA testing opportunities may have affected the biological aggressiveness of PCa at the time of detection. Considering that standard reports indicate that high-risk PCa is relatively more prevalent in older men than in younger patients,[26,27] the apparent difference in average age between the two residential areas suggests that earlier PSA testing opportunities may lead to earlier detection at a lower risk stage.

The authors acknowledge the limitations of this study. First, although we attempted to collect data representing national trends, we were only able to collect data from patients who accounted for 37.9% of all PCa cases at the time of diagnosis during the study period. However, this percentage reflects the examination behavior in actual medical settings

in South Korea, where approximately half of the prostate biopsies are performed in small hospitals that are not at the level of general hospitals. Therefore, it appears that most hospitals with personnel capable of collecting data participated. Second, owing to the limitations of observational multicenter studies, missing values occurred in the information essential for risk stratification. For example, 9.6% of the initial PSA levels, the most crucial factor in PCa prognosis, were missing. Consequently, in the current medical guidelines that classify low-risk cancers as those with all three risk-stratification categories (including PSA, clinical stage, and ISUP grade group) within the standard, too many patients may be defined as intermediate risk. This study classified ambiguous cases as "potential low-risk" if they met one or more low-risk criteria, thereby preventing them from being classified as intermediate-risk. Third, the number of patients with PCa and social awareness in South Korea in the 2010s was estimated to be relatively lower than those in the 2020s. Therefore, the patients' judgment and behavioral patterns for prostate biopsy assessed over time may differ somewhat from those of the present study. This study attempted to compensate for this limitation by incorporating more recent data, capturing 29.4% of all nationally registered patients with PCa in 2010, 36.1% in 2016, and 43.5% in 2020.

In conclusion, this study found that the risk shift toward lower-risk PCa—observed in the United States since the early 2000s following widespread PSA testing—did not occur in South Korea in the early 2010s. At the time of diagnosis, approximately half of the patients nationwide were classified as high-risk. Furthermore, the relatively greater proportion of low-risk disease among residents of the capital metropolitan area, in contrast to the relatively higher prevalence of high-risk cases among rural residents, indicates disparities in access to PCa screening and detection.

ACKNOWLEDGMENTS

The abstract of this paper was selected as the best presentation for the Korean Society of Urology at COEX in October 2024.

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