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The Risk of Biopsy-detectable Prostate Cancer using the Prostate Cancer Prevention Trial Risk Calculator in a Community Setting

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Summary

Objectives—Recent prostate cancer (PCa) screening guidelines suggest that PCa risk should prompt consideration for prostate biopsy. The Prostate Cancer Prevention Trial Risk Calculator (PCPTRC) is the most widely used online risk assessment tool for PCa and high-grade PCa (Gleason score ≥ 7), yet little is known about expected values for the average US male. The purpose of this study was to estimate PCPTRC PCa and high-grade PCa risks for a sample of community men.

Methods and materials—Risks of PCa and high-grade PCa were evaluated using the PCPTRC in an age-stratified random sample of 1,021 Caucasian and African-American men with no previous diagnosis of PCa, aged 55 to 74 years, residing in King County, Washington, USA.

Results—Median PCPTRC risks of PCa (high-grade PCa) were 15.6% (1.2%), 18.7% (2.0%), 18.5% (2.2%), and 26.4% (5.1%) for 55–59, 60–64, 65–69, and 70–74 year old men, respectively. 25.2% of men aged 55–59 had a 25% or greater PCPTRC risk of PCa; this increased to 53.1% in men aged 70–74. 9.4% of men aged 55–59 had a 6% or greater PCPTRC risk of high-grade PCa, increasing to 44.1% in men aged 70–74.

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Conflicts of interest: None

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Conclusions—PCPTRC risk of PCa in a community of US males is high and confounded with over-detected cancers. In contrast, average community PCPTRC risk of high-grade disease is low and increases gradually by age and may better serve for counseling purposes.

Keywords

Prostate Cancer Prevention Trial Risk Calculator (PCPTRC); Prostate cancer; High-grade prostate cancer; Prostate specific antigen (PSA)

Introduction

Following published results of two large randomized prostate-specific antigen (PSA)-based screening trials for prostate cancer (PCa): a European trial finding a 20% risk reduction in cancer-specific mortality due to screening [1] and an inconclusive US-based trial [2], the US Preventative Services Task Force has now issued revised PCa screening guidelines recommending against PSA testing. [3] Concurrently, the American Cancer Society recommends PSA testing and individualized PCa risk assessment for men over 55 as well as for younger men with a history of PCa among family members. [4] Many PCa risk assessment tools are currently available. Two of the most widely used are the Prostate Cancer Prevention Trial Risk Calculator (PCPTRC) [5] and the European Randomized Study of Prostate Cancer (ERSPC) Risk Calculator [6]. [7] Both have been multiply validated across international cohorts. [8–9] The PCPTRC is more widely used because it does not require an assessment of prostate volume and is the only calculator available online for high-grade PCa risk prediction.

The most commonly-asked question from clinicians who use a risk assessment tool for PCa is “What risk level should I use to refer a patient for prostate biopsy?” The information essential to support an informed biopsy decision for a man undergoing PSA-based PCa screening should include 1) his individual risk of PCa, 2) his individual risk of high-grade PCa, and 3) the relative severity of his individual risk compared to his peers, i.e., where his risk stands in relation to men of similar age and ethnicity. Items 1 and 2 necessitate continued efforts to improve accuracy of risk prediction for PCa, and most importantly, high-grade PCa. [10] Item 3 entails a new perspective for interpretation of risk estimates, in particular when they are elevated by over-diagnosis, by measuring against a reference, which is similar to the way age- and gender-specific body mass index percentiles are currently used for screening for obesity in children. This study aimed to address item 3, and was designed to provide the context and reference values needed to compare a man’s individual risk to that of other men of his age or ethnicity using the PCPTRC, the most widely accessible prostate screening tool in contemporary urologic practice.

Unfortunately, to date, the only populations that have been studied and reported on for the PCPTRC are men who are pre-screened, currently undergoing annual PSA screening, or being evaluated for urologic symptoms. [11–16] In contrast, a random sample from a community-based population would provide the most appropriate reference for a typical man. To address this gap, this study used an age-stratified community cohort to evaluate PCPTRC risks of PCa and high-grade PCa (Gleason score ≥ 7).

Materials and Methods

Subjects

Data from Caucasian and African-American men residing in King County, WA, who had served as controls in two case-control studies of PCa were included in the analysis. Study design of the two case-control studies has been described elsewhere [17–18]; briefly,

controls were identified by random digit dialing and age-matched to cases in 5-year groups. After contact by telephone and confirmation of no previous diagnosis of PCa, participants visited a community clinic, where they participated in a structured, in-person interview and had a PSA test and digital rectal examination (DRE) performed. Data from 1,021 controls aged 55–74 years with all risk factors measured for risk analysis (age, ethnicity, PSA, DRE, family history of PCa and prior prostate biopsy history) were included in the present study; controls were not biopsy-confirmed. The two case-control studies were approved by the Fred Hutchinson Cancer Research Center Institutional Review Board.

Statistical Analysis

Descriptive statistics were used to summarize the patient characteristics of the King County cohort and the results were compared to the men in the placebo arm of the PCPT upon which the PCPTRC was developed. Distribution of PSA was summarized using boxplots and location statistics, and risks of PCa and high-grade PCa were calculated using the PCPTRC; these data were also analyzed for African Americans and Caucasians, and for four age strata (55–59, 60–64, 65–69 and 70–74), respectively. Associations between categories of PSA, cancer risk, race and age were examined using the Fisher's exact test or the Pearson chi-square test for large sample sizes. The same associations, treating PSA and cancer risks as continuous variables, were examined using the Mann-Whitney or Krushal-Wallis tests as appropriate. Statistical tests were performed at a two-sided 0.05 significance level using R version 2.9.2.

Results

Characteristics of the King County cohort are summarized in Table 1. When compared to men in the PCPT, men in the King County cohort were younger, had lower rates of family history of PCa and normal DRE, and generally lower levels of PSA (all p values <0.001).

Median PSA values for the 986 King County Caucasians and 35 King County African Americans were 1.2 and 1.1 ng/mL, respectively ($p=0.61$), and 1.0, 1.2, 1.25, and 1.95 ng/mL for men aged 55–59, 60–64, 65–69, and 70–74, respectively ($p<0.001$, Figure 1A). Table 2 shows that about half of the King County cohort had a PSA above 1 ng/mL and this proportion increased as men aged, reaching 72.6% for men in their early 70s. Similarly, while 8.9% of all men had a PSA above 4.0 ng/mL, this proportion increased from 5% in men 55–59 to 17.8% for men in their early 70s.

In the King County cohort, median PCPTRC risks of PCa were 18.6% for Caucasians, 16.6% for African Americans ($p=0.88$) and 15.6%, 18.7%, 18.5%, and 26.4% for men aged 55–59, 60–64, 65–69 and 70–74, respectively ($p<0.001$, Figure 1B). Median PCPTRC high-grade PCa risks were 1.9% for Caucasians, 3.5% for African Americans ($p=0.71$) and 1.2%, 2.0%, 2.2%, and 5.1% for men aged 55–59, 60–64, 65–69 and 70–74, respectively ($p<0.001$, Figure 1C). Table 3 displays the cumulative distributions of PCa and high-grade PCa PCPTRC risk in the King County cohort. As can be seen, almost two-thirds of men had at least a 15% risk of biopsy-detectable PCa according to the PCPTRC; more than one-quarter of men had a PCPTRC risk of PCa above 30%; 37% of men aged 55–75 had a 3% or greater PCPTRC risk of high-grade PCa. While 16.6% of men aged 55–59 had a 30% PCPTRC risk of PCa, this proportion increased to 44.1% for men in their early 70s. There was a greater PCPTRC risk of high-grade PCa with age: 4.2% of men aged 55–59 had a 10% or greater PCPTRC risk of high-grade PCa. This fraction increased to 31.7% for men aged 70–74.

Comment

The answer to the question of what PCPTRC risk level should be used to refer a patient to biopsy is complex and should be based upon physician-patient expectations, the patient's age/life expectancy, the underlying biology of PCa, a highly variable tumor ranging from indolent to aggressive and lethal, as well as the considerable risk of over-diagnosis.

The levels of PCPTRC risks found in this study can provide important information for the clinician struggling with whether to refer a patient for further evaluation. Consider for example, a 55 year old Caucasian man has a PSA of 2.5 ng/mL. If he has no other risk factors for PCa, his PCPTRC risk of PCa is 26.5% and PCPTRC risk of high-grade PCa is 3.3%. While a one-in-four chance of cancer may seem high, the patient can be told that 25% of 55–59 year-old men in the population have at least this PCPTRC risk of finding cancer on prostate biopsy. This conversation may be augmented by the provision of his PCPTRC risk of high-grade PCa (3%) which could be a reason to consider a biopsy. However, 23% of the King County men of similar age have at least this PCPTRC risk of high-grade PCa. In addition, the 2008 age-adjusted U.S. death rate of PCa for Caucasian men with age<65 is 22.82 per 100,000. [19] The clinician could then discuss the 2–4% risk of infection or sepsis with biopsy, the sexual, urinary, and bowel complications of treatment as well as the need for repeated biopsies and careful follow-up if surveillance were selected.

This study also shows the potential risk of unnecessary biopsy and over-detection of disease with PSA-based PCa screening. To put this in perspective, physicians commonly recommend biopsy for a PSA above 4.0 ng/mL as the cancer risk is 25 to 35 percent when PSA is between 4.1 and 9.9 ng/mL. [20] Examining Table 3, 34.5% of men between 55–74 have a PCPTRC PCa risk of at least 25%. This means more than a third of the U.S. population should consider prostate biopsy if a 25% or greater PCPTRC risk of PCa is used as a threshold for biopsy, which would have an extraordinary impact on public health and health care cost. In addition, it can be easily seen that the disease that is most commonly detected is not high-grade (Gleason 6 and less tumors) because of the low median PCPTRC risk of high-grade PCa was obtained for each racial and age category. This preferential detection of these often-indolent tumors reemphasizes the risks of PCa over-detection.

Another important observation of this study relates to the relationship of age and PCPTC risk of high-grade PCa. If one posits that a fraction of high-grade tumors will metastasize and cause death within a period of time (say, a decade), it is most troubling that the risk of these tumors is substantially greater in older men. For example, only about 4% of men in their late 50s have at least 10% PCPTRC risk of these high-grade tumors while 32% of men in their early 70's have these tumors (Table 3). As the life expectancy of a 70 year old man is more than 13 years [21], these data raise the question of whether more careful assessment of older men for risk of high-grade PCa should be considered. Supporting this question is the observation that the median age of death from PCa in the U.S. is 80. [19]

This study has a number of limitations. First, risk in the King county cohort as estimated by the PCPTRC is purely an empirical best guess based on a previous US population participating in a clinical trial. Although the PCPTRC requires minimal clinical data for risk prediction, it does not provide the most accurate risk estimates for PCa or high-grade PCa, a common problem for all PSA-driven risk assessment tools. [22] Other PSA risk assessment tools may improve the accuracy of risk prediction to some extent, but they involve more specialized inputs that are not routinely collected, including prostate volume [6, 23–24], the urinary prostate cancer gene 3 (PCA3) [10, 24–25], or %freePSA [23, 26]. In addition, recent studies show that observed risk PCa risk profiles vary greatly by amount of prior screening or clinical work-up. [22] Continued efforts are needed to improve PCa risk

calculators by incorporating new biomarkers, as well as to standardize calibration studies of such calculators by accounting for work-up bias. Second, because only 3% were African Americans in this study, the results are not generalizable to other communities with a different racial and ethnic composition. More future diverse community studies are needed. Third, in the PCPTRC, Gleason scores ranging from 7 to 10 were considered high-grade, but many contemporary studies include only Gleason scores higher than 7. Lastly, this study was not designed to assess the impact of comorbidities on prostate biopsy decision-making.

Despite these and other potential limitations, the current study represents a valuable contribution to the urologic literature. The findings provide a new perspective for utilizing a widely accessible risk assessment tool, the PCPTRC, by measuring the position of an individual PCPTRC risk to a reference population. There has been no publication of average PCPTRC risk rates, or indeed of any PCa risk assessment tools, in a general community, but rather only in relatively healthy screening cohorts (which would have lower risks of biopsy-detectable PCa) or clinical referral centers (which would have higher risks). Future studies should examine and report from this perspective in the ongoing efforts to make quantitative medicine more amenable to patients.

Conclusions

PCPTRC risk of PCa in a community of US males is high and confounded with over-detected cancers. In contrast, average community PCPTRC risk of high-grade disease is low and increases gradually by age and may better serve for counseling purposes.

Acknowledgments

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Abbreviations

PCPT	Prostate Cancer Prevention Trial
PCPTRC	Prostate Cancer Prevention Trial Risk Calculator
PSA	Prostate Specific Antigen
PCa	Prostate Cancer
High-grade PCa	High-grade Prostate Cancer (Gleason score ≥ 7)
DRE	Digital Rectal Examination

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Figure 1.

Boxplots of PSA and PCPTRC risks of PCa and high-grade PCa by age groups among the 1,021 King County cohort.

31 (3.0%) PSA's beyond 8 ng/mL and 22 (2.2%) PCPTRC high-grade PCa risks above 32% are not shown to improve readability.

Table 1

Participant characteristics of the King County cohort and the PCPT

Characteristic	King County cohort ^a (n=1,021)	PCPT cohort ^b (n=5519)	P value
Age (year)			<0.001
Median	61	70	
55 – 59	361 (35.4%)	38 (0.7%)	
60 – 64	350 (34.3%)	1143 (20.7%)	
65 – 69	164 (16.1%)	1741 (31.5%)	
70 or older	146 (14.3%)	2597 (47.1%)	
Race			<0.001
Caucasian	986 (96.6%)	5276 (95.6%)	
African American	35 (3.4%)	175 (3.2%)	
Other	0 (0%)	68 (1.2%)	
Family history ^c			<0.001
No	907 (88.8%)	4599 (83.3%)	
Yes	114 (11.2%)	920 (16.7%)	
Prior prostate biopsy			<0.001
Never had a biopsy	945 (92.7%)	4873 (88.3%)	
At least one negative biopsy	75 (7.3%)	646 (11.7%)	
PSA (ng/mL)			<0.001
0 – 1	468 (45.8%)	1963 (35.6%)	
1.1 – 2	280 (27.4%)	1640 (29.7%)	
2.1 – 3	111 (10.9%)	775 (14.0%)	
3.1 – 4	71 (7.0%)	510 (9.2%)	
4.1 – 6	37 (3.6%)	481 (8.7%)	
>6	54 (5.3%)	150 (2.7%)	
DRE			<0.001
Normal	761 (74.5%)	4968 (90.0%)	
Abnormal/Suspicious	260 (25.5%)	551 (10.0%)	
Gleason score			NA
<7	Not available	954 (78.8%)	
7–10		257 (21.2%)	

Entries are count (%).

^aMen were not biopsy confirmed but served as an age-stratified random sample of men residing in King County who had not been diagnosed with PCa and were eligible for early detection based on the American Cancer Society's PCa screening guidelines.

^bMen were in the placebo arm of the Prostate Cancer Prevention Trial (PCPT) and their data were used to build the PCPT Risk Calculator; the PCPT had as entry criterion PSA 3 ng/mL, normal digital rectal exam (DRE) and no prior history of PCa and men underwent annual screening for PCa with a required end-of-study prostate biopsy at the end of 7 years.

^cWhether a father, brother or son had prostate cancer.

Table 2
Proportion of men with PSA exceeding specified levels for King County cohort as a whole and by ethnicity and age categories

PSA (ng/mL)	All (n=1021)	Caucasians (n=986)	African Americans (n=35)	55-59 yr (n=361)	60-64 yr (n=350)	65-69 yr (n=164)	70-74 yr (n=146)
>1	54.2	54.3	51.4	45.2	53.7	58.5	72.6
>2	26.7	26.8	25.7	18.8	27.4	23.8	47.9
>3	15.9	15.9	14.3	9.7	17.4	12.2	31.5
>4	8.9	8.7	14.3	5.0	10.6	6.1	17.8
>5	6.2	5.9	14.3	3.0	7.7	3.7	13.0
>6	5.3	5.1	11.4	1.9	6.9	3.7	11.6

Table 3

Proportion of men with PCPTRC PCa and high grade PCa risks exceeding specified levels for King County cohort as a whole and by ethnicity and age categories

	All (n=1021)	Caucasians (n=986)	African Americans (n=35)	55-59 yr (n=361)	60-64 yr (n=350)	65-69 yr (n=164)	70-74 yr (n=146)
PCPTRC risk for prostate cancer							
>5%	97.6	97.5	100	97.8	98.0	95.1	99.3
>10%	81.2	81.3	77.1	77.0	82.6	80.5	89.7
>15%	61.8	62.0	54.3	52.6	62.0	65.2	80.0
>20%	46.1	46.3	40.0	37.1	47.7	46.3	64.8
>25%	34.5	34.6	31.4	25.2	36.9	33.5	53.1
>30%	25.8	25.8	25.7	16.6	27.7	25.6	44.1
>35%	18.8	18.6	25.7	10.5	19.7	19.5	36.6
>40%	14.9	14.8	17.1	7.2	15.7	15.2	31.7
>50%	8.7	8.7	8.6	2.5	10.0	7.9	22.1
>75%	0.5	0.5	0	0	0.3	0.6	2.1
PCPTRC risk for Gleason score 7 (high grade prostate cancer)							
>0.5%	88.2	87.8	100.0	82.8	89.7	87.8	98.6
>1%	70.7	70.1	88.6	60.1	72.0	75.0	89.0
>2%	49.3	48.4	74.3	34.9	49.7	54.3	78.6
>3%	37.0	36.1	60.0	23.0	37.7	40.2	66.2
>4%	29.1	28.4	48.6	16.9	29.4	31.7	55.9
>5%	24.5	23.8	45.7	12.7	26.0	24.4	50.3
>6%	20.3	19.6	40.0	9.4	20.6	22.6	44.1
>8%	15.2	14.5	34.3	5.8	15.7	16.5	35.9
>10%	12.4	12.1	20.0	4.2	13.4	11.0	31.7
>20%	5.3	5.0	14.3	1.4	5.1	4.9	15.9
>30%	2.6	2.4	8.6	0.3	3.1	1.8	8.3