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Unscreened Older Men Diagnosed with Prostate Cancer are at Increased Risk of Aggressive Disease

Jeffrey J. Tosoian[1], **Ridwan Alam**[1], **Carol Gergis**[2], **Amol Narang**[2], **Noura Radwan**[2], **Scott Robertson**[2], **Todd McNutt**[2], **Ashley E. Ross**[1], **Danny Y. Song**[1,2], **Theodore L. DeWeese**[1,2], **Phuoc T. Tran**[1,2], and **Patrick C. Walsh**[1]

[1]The James Buchanan Brady Urological Institute and Department of Urology at the Johns Hopkins University School of Medicine, Baltimore, MD, USA

[2]Department of Radiation Oncology and Molecular Radiation Sciences at the Johns Hopkins University School of Medicine, Baltimore, MD, USA

Abstract

Purpose—To evaluate the relationship between PSA testing history and high-risk disease among older men diagnosed with prostate cancer.

Materials and Methods—Records from 1993 to 2014 were reviewed for men who underwent radiotherapy for prostate cancer at age 75 or older. Patients were classified into one of four groups based on PSA testing history: 1) no PSA testing, 2) incomplete/ineffective PSA testing, 3) PSA testing, or 4) cannot be determined. Outcomes of interest were National Comprehensive Cancer Network (NCCN) risk group (i.e. low, intermediate, or high risk) and biopsy grade at diagnosis. Multivariable logistic regression was used to determine the association between PSA testing history and high risk cancer.

Results—PSA testing history was available in 274 (94.5%) of 290 subjects meeting study criteria. In total, 148 men (54.0%) underwent PSA testing with follow-up biopsy, 72 (26.3%) underwent PSA testing without appropriate follow-up, and 54 men (19.7%) did not undergo PSA testing. Patients who underwent PSA testing were significantly less likely to be diagnosed with NCCN high risk cancer (23.0% vs. 51.6%, $p<0.001$). On multivariable analysis, men with no/incomplete PSA testing had more than three-fold increased odds of high risk disease at diagnosis (OR 3.39, 95% CI 1.96-5.87, $p<0.001$) as compared the tested population.

Conclusions—Older men who underwent no PSA testing or incomplete testing were significantly more likely to be diagnosed with high-risk prostate cancer than those who were previously screened. It is reasonable to consider screening in healthy older men likely to benefit from early detection and treatment.

Keywords

Prostate Cancer; High-Risk; Screening; PSA Testing; Older Men

Corresponding: Jeffrey J. Tosoian, James Buchanan Brady Urological Institute, Johns Hopkins University School of Medicine, 600 N. Wolfe Street / Marburg 134, Baltimore, Maryland 21287, jt@jhmi.edu, Phone: 410-955-2139, Fax: 410-614-8096.

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Introduction

Prostate cancer (PCa) remains the second most common cause of cancer death in Western males.[1] PSA-based screening has been shown to reduce mortality from PCa, but the costs associated with widespread screening and overdiagnosis are significant.[2,3] One strategy to reduce harms associated with screening is to focus screening on men with the highest risk of death from PCa. Based on this principle, some advisory organizations have discouraged screening in older men, citing associated risk and limited benefit.[4] There is increasing evidence, however, that such an age-based approach is significantly flawed.

Population-based data have demonstrated that men diagnosed at 75 years or older account for 48% of metastatic cancers and 53% of PCa deaths, despite representing only 26% of the overall population.[5] Moreover, additional studies have shown that when carefully selected, older men with intermediate to high risk cancers who undergo treatment derive gains in life expectancy comparable to younger men.[6–8] Indeed, the proportion of deaths due to PCa is higher in the elderly, despite higher rates of death from competing causes.[5] This phenomenon has been explained by the observation that older men are more likely to harbor high-risk disease at diagnosis.[8–10]

The reason this age-specific relationship with high-risk cancer at diagnosis exists, however, is less clear. Certainly, physiological explanations such as decreased tumor immunity with advancing age could play a role.[11] At the same time, recommendations aimed at curbing the overdiagnosis of low-risk cancers, such as withholding screening from older men, may contribute to underdiagnosis of high-risk cancers.[12] It is possible that older men with high-risk disease were unscreened or were ineffectively screened, and, for example, did not undergo biopsy despite an elevated PSA. Finally, some tumors may have evaded screening for other reasons, such as rapid progression, low PSA production, or simply remaining unsampled on previous biopsies.[13,14] Understanding these questions is critical in order to provide effective screening to those men who need it most.

Methods

We sought to explore these questions in a population of men treated for prostate cancer at age ≥75. At Johns Hopkins, patients requesting a consultation for treatment of prostate cancer after age 73 are traditionally referred to the department of Radiation Oncology. Therefore the Radiation Oncology departmental database was queried for men who underwent radiotherapy for prostate cancer at age 75 or older from 1993 through 2014. Because the database contains age at treatment rather than diagnosis, some men identified by initial query were diagnosed prior to age 75. Patient-level data were retrieved from the database and comprehensive chart review was performed to identify history of PSA-testing, prostate biopsy, and pertinent clinical observations.

For each patient, PSA history was independently presented to two members of the study team blinded to clinical risk data. PSA testing status prior to the diagnostic PSA was categorized as either: 1) no PSA testing, 2) incomplete/ineffective PSA testing (i.e. no biopsy performed despite abnormal PSA value), 3) PSA testing, or 4) cannot be determined.

In cases of disagreement (n=13; 4.5%), the reviewers came to a consensus (n=10) or the subject was classified as Group 4 (n=3). Men with remote PSA testing history were considered untested (Group 1) if no assessment was performed within 5 years of diagnosis. A conventional threshold for biopsy of 4.0 ng/ml was selected a priori based on traditional recommendations.[15]

Because PSA testing without follow-up is equivalent to no testing for purposes of PCa detection, Groups 1 and 2 were combined into a "No/Incomplete PSA Testing" group for analysis. Baseline demographics were assessed in the untested and tested populations using the Chi-squared or Wilcoxon-Mann-Whitney tests as determined *a priori*. The outcome of interest was risk categorization based on National Comprehensive Cancer Network (NCCN) criteria.[16] Biopsy grade group (GG, as recently adapted from Gleason score [GS]) was assessed as a secondary outcome.[17] Multivariable logistic regression analysis was performed for predictors of PSA testing and high-risk cancer; input variables were determined prior to analysis based on clinical likelihood of significance. Statistical analysis was performed using Stata v13.1 (College Station, TX). This study was approved by the Institutional Review Board at the Johns Hopkins Medical Institutions.

Results

During the study period, 300 men underwent radiotherapy at our institution for PCa at age 75 or older. Of these, eight men with missing clinical risk category data (n=5 without Gleason score, n=3 without clinical stage) and two aged younger than age 74 were excluded. Of 290 eligible subjects, the PSA testing history of 16 (5.5%) could not be determined based on available data. The PSA testing status of the remaining 274 men is listed in Table 1. More than half of the study population (54.0%) underwent PSA testing with appropriate follow-up biopsy. Notably, the proportion of men who underwent PSA testing did not significantly differ by time during the study period (Supplementary Table 1), nor did the proportion of men tested before and after the 2008 USPSTF recommendation against screening in men older than 75 years (50.7% vs. 51.4%, p=0.91).

In total, 54 men (19.7%) did not undergo a PSA measurement prior to diagnosis, and 72 men (26.3%) underwent PSA testing but did not undergo appropriate follow-up (e.g. prostate biopsy) for an elevated PSA level; these 126 men comprised the "No/Incomplete PSA Testing" group. The clinical and pathological characteristics of men who did and did not undergo complete PSA testing are listed in Table 2. At the time of diagnosis, men who underwent PSA testing were significantly younger than those who did not (median 76.2 vs. 78.1, $p<0.001$). The median year of diagnosis and the proportion of African-American men did not differ based on PSA testing status, while median PSA at diagnosis was significantly lower (10.2 vs. 6.4, $p<0.001$) in those who underwent PSA testing. Furthermore, men without a history of PSA testing were more likely to be diagnosed with higher clinical stage disease than men with a history of PSA testing (p=0.002).

There were substantial differences in pathologic grade and NCCN risk category among the tested and untested populations. As displayed in Table 2, the PSA testing cohort was significantly more likely to be diagnosed with low-grade disease (GG1 42.6% vs. 16.7%)

and less likely to be diagnosed with high-grade disease (GG4-5 19.0% vs. 41.3%) as compared to the untested cohort. Accordingly, approximately one-half (51.6%) of the untested cohort was diagnosed with NCCN high-risk disease, as compared to 23.0% of the tested cohort. Notably, high-grade cancer was more common among men with palpable disease (≥T2a) on clinical examination (GG4-5: 37.3% vs. 18.9% nonpalpable, p=0.001). The proportion of men diagnosed with high-risk disease increased during the study period (Supplementary Table 1), but this did not reach conventional levels of statistical significance (p=0.14). Analysis considering high-risk disease before and after the 2005 ISUP grading revisions yielded similar results (high risk cancer 30.8% vs. 40.6%, p=0.10).

In a multivariable logistic regression model (Table 3A), the odds of undergoing PSA testing decreased by 20% with each additional year of age (p<0.001). In the multivariable model for high-risk cancer (Table 3B), men who did not undergo PSA testing had more than three-fold higher odds (OR 3.39, 95% CI 1.96-5.87) of being diagnosed with high-risk disease. Considering both analyses, black men were less likely to undergo PSA testing (OR 0.66, 95% CI 0.35-1.24) although this did not reach statistical significance, and more likely to be diagnosed with high-risk cancer (OR 1.92, 95% CI 1.00-3.67). These findings were unchanged when year of diagnosis was treated as a binary variable relative to the 2005 ISUP grading revisions (Supplementary Table 2).

Untested population

Among the 54 men who presented with no history of PSA testing (Group 1), median PSA at diagnosis was 10.7 (IQR 7.5-29.3). We aimed to assess the reason this initial PSA measurement was obtained in the previously untested population (Supplementary Table 3). Of the 30 men in which this could be determined, 17 (56.7%) presented due to urinary symptoms such as obstructive voiding or hematuria, and 9 (30.0%) had an abnormality detected on rectal exam. Four men (13.3%) had a history of PSA testing but had a prolonged lag (>5 years) from the previous PSA to the diagnostic PSA, beginning at ages 70, 71, 73, and 77 years. Among the 75 men who were determined to have PSA testing without appropriate follow-up biopsy, the peak PSA value at which biopsy was not performed had a median value of 7.2 ng/ml (IQR 5.4-11.7).

Tested population

Among the 148 men who underwent complete PSA testing, 102 (68.9%) were diagnosed with either intermediate- or high-risk disease. Potential explanations as to why these cancers evaded earlier detection despite screening are considered in Supplementary Table 4. There was no discernable explanation in 19 men (18.6%); each man had a history of gradually-increasing PSA levels and underwent biopsy following an initial PSA level > 4.0 ng/ml. Among the remaining population, 41 men (40.2%) underwent a previous biopsy that did not detect cancer, 26 (25.5%) had a rapid rise in PSA (> 1 ng/ml/year) preceding diagnosis, and 16 (15.7%) had low PSA-producing tumors (median PSA 2.7 ng/ml, IQR 1.6-3.4).

Discussion

We assessed PSA testing history in men 75 years and older who underwent radiotherapy at our institution for PCa. Our findings indicate that 54% of the study population underwent complete PSA testing (PSA + biopsy as appropriate) prior to diagnosis. Among the population categorized as untested, 54 (43%) men had no PSA measurements preceding their diagnostic test and 72 (57%) underwent at least one PSA test but did not undergo biopsy despite an elevated PSA level. Within this older population, we found that untested men were significantly more likely to be diagnosed with high-risk and high-grade cancer as compared to the tested cohort. These findings support the hypothesis that PSA testing contributes to widely observed age-based disparities.

Scosyrev and colleagues previously reported the striking observation that men diagnosed with PCa at age ≥ 75 account for 53% of PCa deaths, despite comprising only 26% of the population and having a higher risk of death from other causes.[5] This finding is consistent with several sources which indicate that older men are more commonly diagnosed with high-risk and advanced stage PCa.[8–10] The reason for this age-specific difference in risk classification is less apparent, but has been traditionally explained by either more aggressive (i.e. faster-growing) tumors or less frequent PSA testing in older men. Indeed, population-based data have clearly demonstrated that PSA testing is associated with lower-risk and stage of PCa at diagnosis.[18] Traditionally, however, PSA testing in older men has been no less common than in the overall population, making it difficult to distinguish the impact of various factors on age-specific disparities in outcome.[19,20]

The rate of PSA testing observed in this cohort varies depending on how testing is defined. Because we sought to associate PSA testing with risk classification at presentation, we used a definition of complete PSA testing (i.e. PSA testing + biopsy as appropriate), as a measured PSA level without follow-up is no more effective for detecting cancer than no PSA testing at all. Approximately 80% of the cohort had PSA measured, while 54% had complete testing. These bounds are consistent with published screening rates in this population over the study period,[19,20] but it must be emphasized that this study was not performed to estimate screening rates given the size and selection of our population. It is alarming, although consistent with previous data,[21] that 26.3% of the population had a PSA level that was found to be abnormal but did not undergo subsequent biopsy. Certainly in some cases it is reasonable to defer biopsy in older men with a PSA marginally greater than 4.0 ng/ml, and, as such, our study likely overestimates the proportion of men deemed to have incomplete testing/follow-up. Indeed, previous studies have shown than PSA values as high as 10 ng/ml correlate poorly with the presence of prostate cancer in the elderly.[22,23] As such, the median PSA for which biopsy was deferred in this study was 7.2 ng/ml (IQR 5.4-11.7), raising questions as to the appropriate threshold for biopsy in this population.

Altogether, only four men (13.3% of the determinable untested population) had a history of PSA testing which was discontinued several years prior to diagnosis. Conversely, the majority of unscreened older men (56.7% of determinable) had their diagnostic PSA level measured due to presentation with lower urinary tract symptoms or hematuria. The remaining 30% of untested men had PSA measured due to an abnormality on rectal

examination. Overall, two-thirds (67.5%) of the unscreened population had palpable lesions (≥ cT2a) but only 11% harbored extra-prostatic disease (≥ cT3). In general, these men presented with intermediate and high-risk localized disease – cancers which appear to derive the greatest benefit from treatment.[24] Reproducing these findings in external populations would at the very least support the regular rectal examination for men who stand to benefit from local therapy.

Finally, we sought to assess the reason that intermediate and high-risk cancers may have gone undetected in men who underwent regular PSA screening. The finding that 43.3% of these men had a recent negative biopsy highlights the well-documented limitations of prostate biopsy.[25] There is evidence that increased use of MRI-guided biopsy and other technologies could mitigate the risk of false negative biopsy moving forward.[26] Similarly, our finding that 42.3% of men had a rapid PSA increase or low PSA-producing tumor underscores the limited sensitivity of PSA.[13,14] Consistent with previous data,[27] we observed no cases of high-risk cancer in men with a negative rectal examination and serum PSA < 3.0 ng/ml.

There are several limitations of this study which merit discussion. First, this was a retrospective chart review using the database from the Department of Radiation Oncology and was thus subject to missing data or recording error. Furthermore, information on hormone therapy was not considered as part of the current study. Encouragingly, we were able to reasonably determine PSA-testing history in the vast majority of subjects. Second, we lacked comorbidity data such that we were unable to assess the appropriateness of screening in the study patients or derive conclusions about life expectancy. Thus, it is possible that the absence of screening in some men was an informed decision based on the risks and benefits of screening in light of factors not captured in our data. Given all subjects ultimately underwent radiotherapy, however, and our institution has proactively emphasized conservative management strategies,[28] we believe the vast majority of men were fit for treatment – but this cannot be proven definitively under this study design. Moreover, our evaluation of PSA-testing status ultimately included a subjective component. For this reason, we aimed to provide the most objective guidelines possible, such as the use of a PSA threshold of 4.0 ng/ml for biopsy. We also classified testing status as yes/no for analysis, a more apparent distinction than, for example, grading the intensity of screening. The impact of subjectivity appears to have been limited, as reviewer categorization was unanimous in almost all cases (95.5%). Importantly, our outcome of risk classification at diagnosis is not a perfect indicator of long-term oncological outcomes, and we therefore cannot definitively conclude that diagnosis with high-risk disease adversely affected these men with regard to metastatic disease or cancer-specific mortality, particularly in the absence of life expectancy data. On the other hand, there is a strong body of literature describing the association between diagnostic risk classification and longer-term oncologic outcomes.[29,30] Finally, men presenting to our tertiary care referral center for treatment may not represent the general population. Nonetheless, our findings are not meant to provide definitive conclusions, but rather a report of our observations exploring how various approaches to diagnostic testing in older men impact the treated population.

Conclusions

The limitations of PSA testing are well-documented, but abandoning efforts at early detection altogether could prove unacceptably costly in terms of avoidable deaths.[31] Our results from this selected population of men who underwent radiotherapy at age 75 or greater demonstrate that older men without a history of PSA testing harbor a greater than three-fold increased risk of being diagnosed with high-risk disease. Acknowledging that screening should focus on men with the highest risk of prostate cancer death, the healthiest men age ≥75 fall into this category. Thus, we agree with recent NCCN guidelines suggesting that very healthy older men with minimal comorbidity may be considered for screening.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Cohort PSA-Testing History

Group	N	%
1: No PSA testing	54	19.7%
2: Incomplete PSA testing (no follow-up)	72	26.3%
3: PSA testing	148	54.0%
Total	274	

Table 2

Cohort Characteristics at Diagnosis

	No PSA Testing (n=126)	PSA Testing (n=148)	P-value
Median age	78.1 (76.4-80.2)	76.2 (75.3-78.6)	<0.001
Median year of diagnosis	2009 (1999-2011)	2009 (2000-2011)	0.43
Black race	28 (22.2%)	24 (16.2%)	0.21
Serum PSA (ng/ml)	10.2 (7.3-18.4)	6.4 (4.5-10.7)	<0.001
Clinical stage			0.002
T1c	41 (32.5%)	82 (55.4%)	
T2a	36 (28.6%)	34 (23.0%)	
T2b/T2c	35 (27.8%)	21 (14.2%)	
T3a	7 (5.6%)	5 (3.4%)	
≥ T3b	7 (5.6%)	6 (4.1%)	
Biopsy Grade Group			<0.001
GG1 (GS 6)	21 (16.7%)	63 (42.6%)	
GG2 (GS 3+4=7)	28 (22.2%)	35 (23.7%)	
GG3 (GS 4+3=7)	25 (19.8%)	22 (14.9%)	
GG4 (GS 8)	23 (18.3%)	18 (12.2%)	
GG5 (GS 9-10)	29 (23.0%)	10 (6.8%)	
NCCN risk category			<0.001
Low	10 (7.9%)	46 (31.1%)	
Intermediate	51 (40.5%)	68 (46.0%)	
High	65 (51.6%)	34 (23.0%)	

Table 3A

Multivariable Model for PSA Testing

Variable	Odds Ratio (95% CI)	P-value
Age (per 1 year)	0.80 (0.73-0.88)	<0.001
Black race	0.62 (0.33-1.17)	0.14
Year of diagnosis	1.02 (0.98-1.06)	0.25

Table 3B

Multivariable Model for High-Risk Cancer

Variable	Odds Ratio (95% CI)	P-value
Age (per 1 year)	1.05 (0.95-1.15)	0.34
Black race	1.92 (1.00-3.67)	0.049
Year of diagnosis	1.04 (1.00-1.08)	0.08
No PSA testing	3.39 (1.96-5.87)	<0.001