

National Trends in the Management of Low and Intermediate Risk Prostate Cancer in the United States

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Purpose: To our knowledge factors affecting the adoption of noncurative initial management in the United States for low risk prostate cancer on a population based level are unknown. We measured temporal trends in the proportion of patients with low and intermediate risk prostate cancer who elected noncurative initial treatment in the United States and analyzed the association of factors affecting management choice.

Materials and Methods: We identified 465,591 and 237,257 men diagnosed with low or intermediate risk prostate cancer using NCDB and SEER (2004 to 2010), respectively. We measured the proportion of men who elected noncurative initial treatment and used multivariate logistic regression analysis to evaluate factors affecting the treatment choice.

Results: During the study period noncurative initial management increased in patients at low risk from 21% to 32% in SEER and from 13% to 20% in NCDB (each $p < 0.001$). This increase was not reflected in our overall study population (SEER 20% to 22% and NCDB 11% to 13%) since the proportion of patients with Gleason score 6 or less decreased with time (61% to 49% and 61% to 45%, respectively). From 2004 to 2010 older age, lower prostate specific antigen, earlier clinical stage, increased comorbidity index and not being married were associated with a higher likelihood of noncurative initial management (each $p < 0.05$).

Conclusions: Two independently managed, population based data sets confirmed a temporal increase in noncurative initial management in patients with low risk PCa that did not translate into greater use overall in those at low and intermediate risk combined. These contrasting results are likely due to grade migration resulting in fewer men being classified as with low risk PCa based on Gleason score.

Key Words: prostate, prostatic neoplasms, SEER program, risk, trends

In an 18-year followup report of men with localized PCa the risk of non-cancer death was dramatically higher than that of PCa death, especially in patients at low risk.¹ To decrease overtreatment and potential treatment associated morbidity multiple groups have investigated NCIM approaches in select patients.²⁻⁴ A NCIM strategy termed active surveillance

showed approximately 97% cancer specific survival 10 years after diagnosis with most men remaining on observation and not requiring surgery or radiation.² This growing body of evidence prompted multiple guidelines to recognize NCIM as a strategy for low risk PCa, defined as PSA less than 10 ng/ml, Gleason score 6 or less and cT1-T2a.⁵⁻⁷

Abbreviations and Acronyms

ADT = androgen deprivation therapy

CCI = Deyo-Charlson comorbidity index

NCDB = National Cancer Database

NCIM = noncurative initial management

NOS = not otherwise specified

PCa = prostate cancer

PSA = prostate specific antigen

SEER = Surveillance, Epidemiology and End Results

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NCIM adoption through 2004 was modest with 1 study showing a rate of less than 10% in low risk cases.⁸ In addition, ISUP (International Society of Urological Pathology) modified the Gleason scoring system in an effort to homogenize the definition of Gleason pattern 3 by making any cribriform pattern Gleason 4.⁹ This may explain the recent grade migration in the United States, leading to fewer cases qualifying as low risk Gleason 6.¹⁰ Normally attributable to patient preference, NCIM underuse was highlighted in a 2011 NIH (National Institutes of Health) consensus statement.^{11,12} It mentioned patient and societal factors as important aspects of future research to understand decision making for low risk PCa management.¹¹

We used 2 independently managed national databases to analyze the characteristics of patients with low and intermediate risk PCa between 2004 and 2010. We determined the proportion of men who met eligibility criteria for and elected NCIM, and we evaluated factors affecting the choice of NCIM.

MATERIALS AND METHODS

After acquiring institutional review board exemption we extracted data on 2004 to 2010 from SEER and NCDB. SEER represents 28% of cancers in the United States and captures all cancers in defined geographic regions while NCDB acquires data on 70% of cancers in the country from participating hospitals.^{13,14} The 2 databases were previously used as reliable sources of trends in PCa management and risk profiles.^{15,16}

We identified all patients diagnosed with non-metastatic PCa (SEER 388,425 and NCDB 846,965), PSA 20 ng/ml or less (SEER 64,124, information missing on 324,301 and NCDB 119,903, information missing on 658,952), Gleason score less than 8 (SEER 14,518, information missing on 246,973 and NCDB 35,328, information missing on 846,965) and cT1-2 disease (SEER 2,124, information missing on 241,870 and NCDB 59,968, information missing on 470,669) as well as known data on treatment (SEER 237,271 and NCDB 465,591) and patient age (SEER 37,257 and NCDB 465,591). Although each database extends through 2011, data on patients diagnosed in 2011 were not analyzed because at least a year of followup was required to determine initial treatment.

Using National Comprehensive Cancer Network® risk groups⁷ low risk PCa was defined as PSA less than 10 ng/ml with Gleason score 6 or less. In NCDB and SEER PSA is recorded as the highest value before the diagnostic procedure or if unavailable the earliest pretreatment but post-diagnostic value.¹⁷ Before 2010 Gleason score was recorded in each database as clinical grade or if available pathological grade after radical prostatectomy. For consistency we used this method for patients diagnosed in 2010. Cases with PSA 10 to 20 ng/ml or Gleason 7 were labeled as intermediate risk.

Primary treatment was defined as management within 1 year of diagnosis. Radiation included external

beam radiotherapy or brachytherapy. The code for surgery shared by the databases included prostatectomy, cryosurgery, laser ablation and hyperthermia, and transurethral resection of the prostate. Because transurethral prostate resection has no curative intent, it was not considered surgery.

In SEER if neither surgery nor radiation was indicated, a NCIM approach such as active surveillance or passive watchful waiting was considered the management strategy. In NCDB ADT is also recorded and it was not considered NCIM. NCDB also allowed us to determine the time between diagnosis and all treatments. We performed sensitivity analysis defining NCIM as no treatment for 6 months to determine whether the NCIM trends were similar with a less conservative cutoff.

Patient, cancer, temporal and geographic factors were analyzed for an association with NCIM. The factors included age, marital status, race, clinical stage, PSA, CCI,¹⁸ diagnosis year and geographic location. In SEER married and unmarried/domestic partner patients were considered married while single, separated, divorced or widowed patients were labeled not married. Facility type was based on the number of patients with PCa encountered each year, including community—greater than 100, comprehensive—greater than 500 and academic—greater than 500 with graduate medical training offered.

Multivariate logistic regression analysis was done to determine relationships between independent variables and NCIM use as the dependent variable. All variables measured were included on the final multivariate analysis. Additional multivariate logistic regression analysis was performed to compare the proportion of men with low risk PSA (less than 10 ng/ml), Gleason score (6 or less) or nonpalpable clinical stage (T1) by independent variable diagnosis year (2010 vs 2004). To account for temporal changes in age and race they were also included as independent variables on analysis. All ORs and p values were derived from our multivariate logistic regression analysis with $p < 0.05$ considered statistically significant. All statistical analysis was done with STATA® 12.0 software using the logistic command for all multivariate analyses.

RESULTS

Supplementary table 1 (<http://jurology.com/>) shows initial management, demographics and tumor characteristics. In each data set almost half of the patients were diagnosed between ages 60 and 69 years, and approximately 70% were white non-Hispanic. Most patients with low risk PCa (SEER 77.1% and NCDB 60.3%) and intermediate risk PCa (58.9% and 60.3%, respectively) had PSA between 4 and 10 ng/ml.

NCIM use in men with low risk PCa in SEER increased from 21% (3,630 of 16,960) to 32% (5,020 of 15,510) (2010 vs 2004 OR 1.89, 95% CI 1.79–1.99, $p < 0.001$, supplementary table 2, <http://jurology.com/> and fig. 1, A). NCIM in men with intermediate risk PCa decreased from 18% to 14% (2010 vs 2004 OR 0.91, 95% CI 0.86–0.97, $p = 0.006$,

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