



Contemporary Management of Incident Prostate Cancer in Large Community Urology Practices in the United States

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OBJECTIVE	To characterize the contemporary management of prostate cancer patients in large community practices. The optimal management of incident prostate cancer has changed in the last decades to include active surveillance for a large number of men. At the same time, many community practices have merged into larger groups. The adoption of evidence-based guidelines is of increasing importance, but poorly understood in this newer practice setting.
METHODS	We conducted a retrospective chart review of men ≤ 75 years old with very low, low, and intermediate risk incident prostate cancer diagnosed between December 1, 2012 and March 31, 2014, in 9 geographically distributed large urology practices. We used descriptive statistics and multivariable regression to assess predictors of primary management choice.
RESULTS	2029 men were in the study cohort. A majority were white (68.7%). Total of 45.7% had intermediate risk, 36.2% low risk, and 17.9% had very low risk disease cancer. Active surveillance (AS) was the initial treatment for 74.7% of men with very low risk disease, 43.5% of men with low risk disease and 10.8% of men with intermediate risk disease. The probability of choosing surgery vs radiation for men with lower and intermediate risk disease was 0.54 (95% confidence interval: 0.42, 0.65) and 0.59 (95% confidence interval: 0.48, 0.69), respectively.
CONCLUSION	We found that the initial management of lower risk prostate cancer in large community urology practices largely followed clinical characteristics, widespread adoption of active surveillance, and equal use of surgery and radiation. However, some variation by practice suggested a need for further investigation and continued improvement. UROLOGY 129: 79–86, 2019. © 2019 Elsevier Inc.

The optimal management of newly diagnosed prostate cancer has changed substantially in the last decades to recognize the importance of active surveillance (AS) and observation for a large number of men within the biologic spectrum of lower risk (National Comprehensive Cancer Network (NCCN) very low and low risk) prostate cancer.^{1,2} Multiple studies have examined the initially slow rate of adoption of guideline recommendations to offer AS to men with lower risk prostate cancer, though few studies have focused entirely on community (private) practices, and those that have, focused

on limited geographic regions or single practices, and very few have presented contemporary data.³⁻⁷

The rate of adoption of evidence-based guidelines, as a key component for delivering value based care, is of rising interest to multiple stakeholders: clinicians, researchers, payers, and health policy decision-makers, and is a central focus in recent national payment reform efforts. According to the American Urological Association Annual Census, nearly two-thirds (59.5%) of urologic care in the US is delivered by community practices. Many community practices have recently undergone significant consolidation, such that large practices (>10 providers) account for 25% of all urologists in the US and an estimated 30% of urologic care.⁸ Little is known about the management of prostate cancer patients in this setting, however the fee-for-service delivery model, inclusive of urologic care, has been criticized for promulgating a health economic model whereby healthcare provider financial interests may not always align with metrics of patient outcomes and healthcare savings.⁹⁻¹² Accordingly, a central goal of recent

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federal health policy changes has been to better align payment with quality of care in order to foster the 'triple aim' of healthcare reform: improving care and health, while reducing cost.^{13-17,28,29}

Despite the widespread adoption of electronic medical record systems, understanding practice patterns for these evolving models within community urologic practice has remained challenging due to the persistently siloed and unstructured nature of healthcare data. Practiced-based research and implementation science have been cited as important ways to improve our understanding of how healthcare is delivered.¹⁶ Accordingly, the Large Urology Group Practice Association Active Surveillance Benchmarking Project, through an unrestricted grant by Genomic Health, Inc., sought to review and describe contemporary practice patterns in 9 geographically distributed large community urology group practices to provide the insight necessary to improve practice patterns.

MATERIALS AND METHODS

The primary objective of the study was to assess the utilization of AS among men with lower risk prostate cancer (very low and low risk combined). A secondary objective was to examine utilization rates of surgery and radiotherapy interventions for a large contemporaneous cohort of newly diagnosed localized prostate cancer patients within a diverse US geographical distribution. Nine member practices from Large Urology Group Practice Association participated in this study: Atlantic Urology Clinics, Myrtle Beach, SC; Carolina Urology Partner, Charlotte, NC; Genesis Healthcare Partners, San Diego, CA; Oregon Urology Institute, Springfield, OR; Skyline Urology, Los Angeles, CA; Urology of Indiana, Indianapolis, IN; The Urology Center of Colorado, Denver, CO; The Urology Group, Cincinnati, OH; and Virginia Urology, VA.

We conducted a retrospective chart review of all men with newly diagnosed prostate cancer between January 1, 2013 and March 31, 2014. AS was defined by documentation of AS within 6 months of diagnosis, or absence of curative therapy with continued follow-up of at least 1 PSA and office visit beyond 6 months. Each practice had its own protocol for AS. Only men diagnosed by prostate biopsy at the participating practices were included, while those with high-risk disease or who were 75 years or older were excluded from the study. Patients without documented primary therapy or without follow-up of at least 6 months were excluded. Each participating practice assigned 1 or 2 employees to perform chart abstraction. All abstractors were trained by the principal investigator (JS) and abstraction was overseen by practice clinician champions and JS. We employed the NCCN definitions of prostate cancer disease risk group from 2013 (very low risk = T1c, Gleason 6, PSA <10, 1-2 biopsy cores positive with <50% cancer in any 1 core, and PSA density <0.15 ng/mL; low risk = T1-T2a, Gleason 6, PSA <10; intermediate risk = T2b-T2c or Gleason 7 or PSA 10-20).¹⁸ Practice characteristics were assessed by surveying practice leadership. Abstracted data was validated by an independent professional medical abstraction firm (CIOX, Atlanta, GA) through a random sample of

20 cases from 6 of the 9 participating practices. In 3 practices, administrative and legal concerns about Health Insurance Portability and Accountability Act of 1996 and related law, and data ownership prevented outside/remote access to the medical record. Only deidentified data was analyzed and IRB approval was obtained.

Descriptive statistics including Chi-square (Fisher's exact tests when necessary) and median tests were used to characterize the study cohort and to compare the use of initial AS to use of curative therapy and, among those who chose curative therapy, to compare the use of surgery to radiotherapy according to relevant patient and histopathologic characteristics. The association between predictor variables and use of AS, and choice of curative therapy was further evaluated with a multivariable random effects regression model adjusting for age, race, and risk group (Table 2). Sensitivity testing of risk group classification vs its individual components showed that Gleason score and PSA were both independently associated with choice of AS (odds ratio [OR] 2.95, $P < .001$ for 3 + 3 vs 3 + 4; OR 1.93, $P = .002$ for PSA <10 vs PSA 10-20. To limit colinearity, only the summative risk group classification was used in the final regression model. To assess variation in primary management between practices we derived the adjusted proportion of patients undergoing AS, surgery and radiation in each practice from multivariable model. All statistical testing was performed using SAS v.9.4 (SAS Institute Inc., Cary, NC) or Stata v.13.1 (StataCorp, College Station, TX) at the 5% significance level. This study was funded in part by an unrestricted grant from Genomic Health, San Francisco, CA.

RESULTS

Nine practices, representing over 235 urologists involved in prostate cancer care, in 7 states, participated in the study. Practices ranged in size from 12 to 50 physicians with a median of 30.

Of 2070 patients meeting inclusion/exclusion criteria, 41 were excluded for missing treatment information, leaving a total of 2029 patients included in the study cohort. Demographic data are shown in Table 1. The majority of patients were white (68.7%) and most were over 55 years old (86.1%). Patients were most frequently diagnosed with NCCN intermediate risk disease (927; 45.7%), followed by low risk (734; 36.2%) and very low risk disease (364; 17.9%). Overall, 34.2% (693) of men chose AS, 36.3% (737) surgery, 26.5% (538) radiotherapy, and 3.0% (61) other (cryotherapy, high intensity focused ultrasound, or androgen deprivation therapy). AS was the initial management choice for 74.7% (272) of men with very low risk disease, 43.5% (319) of men with low risk disease, and 10.8% (100) of men with intermediate risk disease (Table 1). On univariate analysis, the use of AS decreased with increasing disease risk group classification. Gleason score, PSA, PSA density, T stage, and younger age all $P < .001$; while the use of interventional therapies, surgery vs radiation, increased with younger age ($P < .0001$), lower PSA ($P < .0003$), and lower PSA density ($P = .0164$). Use of AS and interventional therapies varied by practice, with utilization of AS ranging from 41% to 75% among men with lower risk disease.

Multivariate analysis, (Table 2), showed significant predictors for choice of AS vs other therapies were risk group (OR 28.84, 95% confidence interval [CI] 20.59-40.38 for very low vs intermediate risk disease and OR 7.34, 95% CI 5.58-9.64 for low vs

Table 1. Patient characteristics by primary treatment among of men with incident prostate cancer diagnosed between January 1, 2013 and March 31, 2014. Calculated percentages are by row. (PSA in ng/mL, PSA Density is ng/mL/cc)

Row Percentage, % (n)	Total (N = 2029)	AS 34.2 (693)	Surgery 36.3 (737)	Radiotherapy 26.5 (538)	Other 3.0 (61)	AS vs Treatment P	Surgery vs Radiotherapy P
Age							
≤55	281	30.3 (85)	53.7 (151)	15.0 (42)	1.1 (3)	.0008	<.0001
56-65	912	31.0 (283)	42.1 (384)	24.6 (224)	2.3 (21)		
66-75	836	38.9 (325)	24.2 (202)	32.5 (272)	4.4 (37)		
Race							
White	1394	35.2 (490)	36.2 (504)	25.5 (356)	3.2 (44)	.0211	.5617
AA	335	27.2 (91)	37.0 (124)	31.9 (107)	3.9 (13)		
Other	252	36.5 (92)	36.9 (93)	25.0 (63)	1.6 (4)		
Missing	48	41.7 (20)	33.3 (16)	25.0 (12)	0.0 (0)		
PSA							
Median (IQR)	5.5 (4.4, 7.3)	5.2 (4.3, 6.9)	5.4 (4.3, 7.2)	5.9 (4.6, 8.0)	6.9 (4.9, 9.3)	<.0001*	.0003*
Range	0.1–19.7	0.1–19.6	0.3–19.5	1.0–19.3	2.3–19.7		
PSA density							
Median (IQR)	0.15 (0.10, 0.22)	0.12 (0.08, 0.18)	0.16 (0.11, 0.24)	0.18 (0.13, 0.25)	0.18 (0.13, 0.25)	<.0001*	.0164*
Clinical T stage							
T1	1561	37.2 (580)	33.6 (524)	26.1 (408)	3.1 (49)	<.0001	.1109
T2	437	21.5 (94)	46.7 (204)	29.1 (127)	2.8 (12)		
Tx	31	61.3 (19)	29.0 (9)	9.7 (3)	0.0 (0)		
Gleason							
3+3	1242	51.6 (641)	27.4 (340)	19.7 (244)	1.4 (17)	<.0001	.8335
3+4	527	8.5 (45)	50.7 (267)	36.4 (192)	4.4 (23)		
4+3	260	2.7 (7)	50.0 (130)	39.2 (102)	8.1 (21)		
NCCN risk							
Very low	364	74.7 (272)	14.0 (51)	10.2 (37)	1.1 (4)	<.0001 [†]	.4887 [†]
Low	734	43.5 (319)	31.5 (231)	23.7 (174)	1.44 (10)		
Intermediate	927	10.8 (100)	49.1 (455)	35.1 (325)	5.1 (47)		

AA, African American.

* Wilcoxon rank sum test.

[†] Fisher's exact test.

intermediate risk disease); and older age (OR 2.25, 95% CI 1.58-3.20 for ages 66-75 vs ≤55). Two practices showed significant differences in baseline use of AS (OR 1.63, *P* value = .025, and OR 2.70, *P* value <.001) while there was no significant difference among the other 7 practices (Figure 1). Race was not correlated with choice of AS. Adjusting for age, race and risk group, the marginal probability of choosing AS was 0.75 (95% CI: 0.66, 0.82) for men with very low risk disease, 0.43 (95% CI:

0.34, 0.53) for men with low risk disease and 0.09 (95% CI: 0.06, 0.14) for men with intermediate risk disease.

We also examined the use of surgery vs radiation (Table 2) and found that age was most strongly associated with utilization of surgery vs radiation; surgery decreased with increasing age among men 56-65 and 66-75 vs ≤55 (OR 0.46 and 0.18, respectively, *P* values both <.001). African-American men utilized surgery less than white (OR 0.55, *P* <.001). Three sites had

Table 2. Multivariate analysis (using mixed effects models) of predictors of utilization of active surveillance vs other (surgery, radiation, and other), and surgery vs radiation among men with newly diagnosed lower risk (very low and low risk combined) prostate cancer and intermediate risk prostate cancer

	Active Surveillance vs Other Therapy (N = 1979)		Surgery vs Radiotherapy (N = 1246)	
	OR (95% CI)	<i>P</i> value	OR (95% CI)	<i>P</i> value
Race (white as referent)				
African American	1.08 (0.78, 1.50)	.643	0.55 (0.39, 0.76)	<.001
Other	1.01 (0.69, 1.49)	.965	0.88 (0.58, 1.33)	.544
Age (≤55 as referent)				
56-65	1.10 (0.78, 1.55)	.578	0.46 (0.31, 0.69)	<.001
66-75	2.25 (1.58, 3.20)	<.001	0.18 (0.12, 0.27)	<.001
NCCN risk group (intermediate as referent)				
Very low	28.84 (20.59, 40.38)	<.001	—	—
Low	7.34 (5.58, 9.64)	<.001	—	—
Lower (very low + low)	—	—	0.80 (0.62, 1.04)	.095

significantly greater utilization of surgery (Fig. 2), however the majority of practices had similar rates of primary therapy choice. The overall estimated probability of choosing surgery vs radiation for men with lower and intermediate risk disease was 0.54 (95% CI: 0.42, 0.65) and 0.59 (95% CI: 0.48, 0.69), respectively.

DISCUSSION

This study of initial prostate cancer management trends in a large geographically distributed cohort of community urology practices, representing 235 urologists and over 2000 patients across 9 practices and 8 states suggest that AS was utilized frequently, but it is likely there is still room for increased use and there is still variation by practice. This study also shows that surgery and radiotherapy were utilized largely as would be expected by patient and disease parameters, however, there is, again, some variation at the practice level. To our knowledge this is the first study to focus on a cohort of large independent US community urology practices.

These findings support other recent studies showing increasing use of AS over the last decade. A recent analysis from the CaPSURE registry showed a dramatic increase from 1990-2009 to 2010-2013 in the use of AS among men with low risk prostate cancer (CAPRA score 0-2) from 6.7%-14.3% to 40.4%.³ Similarly, Womble et al reported that among practices participating in the Michigan Urological Surgery Improvement Collaborative, the rate of AS among men diagnosed with lower risk prostate cancer from March 2012 to August 2013 was 49%, which is very similar to the 53.8% of men with lower risk disease in our cohort whose initial management was AS. A recent study of care in the VA also showed similar, if not slightly lower rates of AS use in 2013 of just under 40%, however when combined with watchful waiting was nearly 70%.⁶ Higher rates of AS were reported in Sweden, where, by 2014 in men 60-69, AS was the initial management choice for 91% with very low risk disease and 74% with low risk cancer. While we cannot draw conclusions from this study about the role of practice setting on adoption rates of AS, this study suggests that large community practice urology groups in the US adopted AS at a rate on par and in some cases exceeding other practices in the US. This is of increased interest given criticisms of financial conflicts in the fee-for-service model and that AS is the least well remunerated treatment pathway for localized prostate cancer. Further analysis is warranted to examine the role of practice setting as well as relative effectiveness of quality improvement programs.

Practice level variation, and by extension geographic variation, are not new. Variation in urologic care delivery was a primary finding in Wennberg's seminal health services paper, published in 1973, which showed a nearly 3-fold variation in prostatectomy (simple vs radical not defined) adjusted for population by geographic area in Vermont in 1970.¹⁹⁻²¹ While the variation by practice in our cohort was largely limited to 2 sites, it is still present.

According to Auffenberg et al the practice level variation in use of AS in Michigan Urological Surgery Improvement Collaborative practices is large, 30.2%-72.6%, but is less than the variation among physicians, 0%-95.6%, and that there was no association with volume on a provider level and choice of AS, suggesting provider level inquiry and intervention may be more fruitful.²¹ Indeed, 1 practice that had previously participated in this study, reported a large improvement in AS utilization for men with very low risk disease, improving from 32% of 58% after a physician level intervention.⁷ At the physician level, conflicts between delivering standardized care and meeting individual patient needs have been elucidated in the setting of AS.²² Further work is warranted to examine community, practice, physician, and patient characteristics. Additionally, the optimal methods for improving the rate of adoption of guideline recommended care need to be defined. Our study lays the groundwork for further examining treatment trends and their etiologies in addition to providing the background against which to benchmark future changes.

Our study found no significant differences in utilization of surgery and radiation by disease parameters, though there was variation as one might expect by age, and a small but significant preference for radiation among African-American men. While there was some practice-level variation, a preponderance of urologists appear to manage prostate cancer by clinical parameters, for example, risk grouping, despite a majority of practices owning and incorporating radiotherapy into their practice. This supports the findings of Harrel et al that greater integration measured at the level of the marketplace led to higher quality of care for men with prostate cancer,²³ and provides an interesting angle through which to view several studies highlighting increased use of radiation therapy, potentially associated with increased urology practice ownership of radiation facilities.^{11,24,25} Our findings suggest that this increase may appropriately follow clinical characteristics and is perhaps a reflection of improved alignment incentives in integrated practices. Defining the appropriate utilization of surgery and radiotherapy in this setting is challenging. We hypothesized, based on studies showing similar efficacy of both modalities, that utilization should be roughly equal. For a majority of practices this was what we found. More work should be done to define the outer limits of normal utilization, as appropriate variation by local and patient factors is likely. Our findings raise the possibility that the increased infrastructure and oversight found in integrated practices might act as an accelerator for adoption of evidence-based guidelines and a bulwark against inappropriate utilization of health-care resources.

The call for more practice-based research is dependent on being able to measure care.¹⁶ Analysis of administrative datasets and large registries has provided much insight, but access is often limited and delays reduce actionability. Data validity of large administrative datasets

has, also, been questioned.²⁶ We hoped the use of EHRs, which were promulgated in part to increase access to data would facilitate the evaluation of contemporary community care patterns. Ironically, while prostate cancer is one of the most common cancers among men, the diagnosis and billing coding systems (the World Health Organization's International Statistical Classification of Diseases and Related Health Problems-10, and the American Medical Association's Current Procedural Terminology codes) were not able to capture either the clinically critical components of cancer staging, nor the selection of noninterventional therapies like AS. Accordingly, we found that manual chart abstraction was the only way to reliably capture clinical care and that the use of EHRs by all participating groups, served only to facilitate manual abstraction. We hope that continued improvement in data capture and exchange as well as efforts like the American Urological Association's Quality Registry will continue to improve access to actionable data for frontline providers.²⁷

There are several limitations to this study. Neither patients nor sites were randomly selected. Practices self-selected out of an interest to better understand their practice patterns, and all newly diagnosed men from each practice were included, except as noted. Data collection was performed by members of each practice who were carefully trained but were not professional

abstractors. Hence, an independent and professional chart abstraction consultancy team was further employed. We were only able to externally validate data from 6 of the original 9 participants, however we have no reason to believe abstraction accuracy differed in these 3 practices and the concordance among the validated groups was very good. Agreement between the primary cohort and validation cohort was 99.2% for age, 77.5% for race, 89.2% for primary therapy choice, and 89.2% for risk group classification. The disagreement over primary therapy was primarily due to different interpretations of when a patient was lost to follow-up vs receiving outside therapy. The discordance in risk group classification was most commonly (62%) due to reclassification of disease risk group from very low risk to low risk (eg T1c vs T2a). We furthermore conducted the primary analyses on both the study cohort (presented) and the validation cohort (not presented) with similar results found. While some missing data could have biased the results, only 203 (9.1%) patients were excluded for lack of information on primary therapy. In Figure 1, both outlying practices were among the 6 externally validated practices, as were 2 of the 3 outlier practices in Figure 2. Our analysis of surgery vs radiotherapy is limited by only 1 of the 9 sites in our cohort having no ownership stake in a radiotherapy center. We did not have access to other variable such as

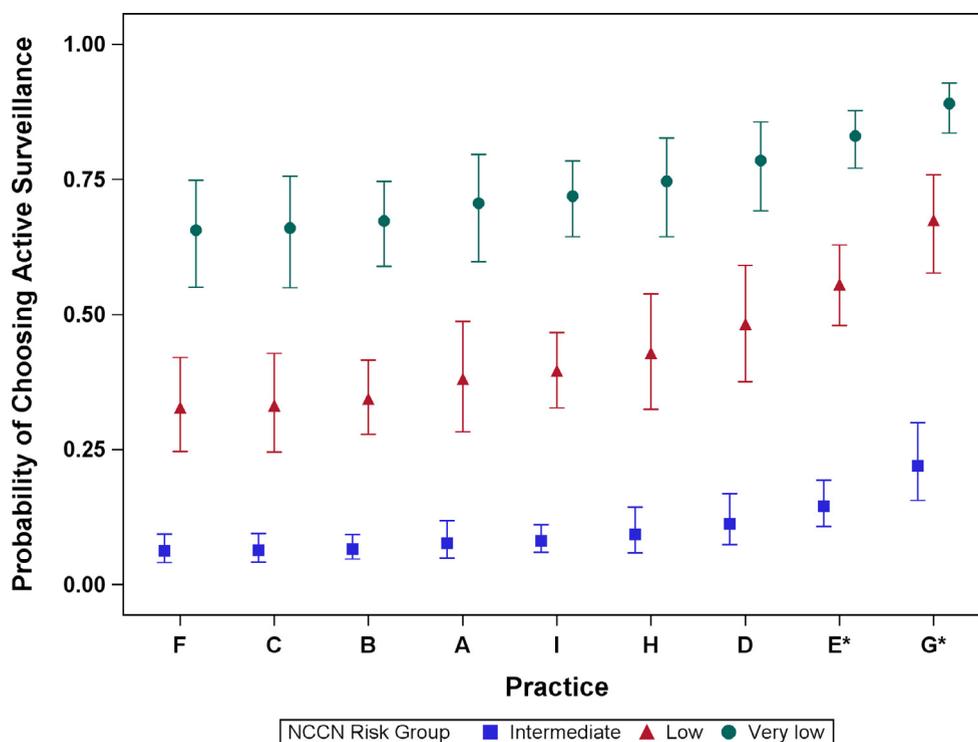


Figure 1. Practice-specific estimated probabilities of active surveillance vs other therapy (surgery, radiotherapy, or other) for men with NCCN very low, low, and intermediate risk prostate cancer. (* = sites with significant variation in the baseline probability of active surveillance compared to other therapy). (Color version available online).

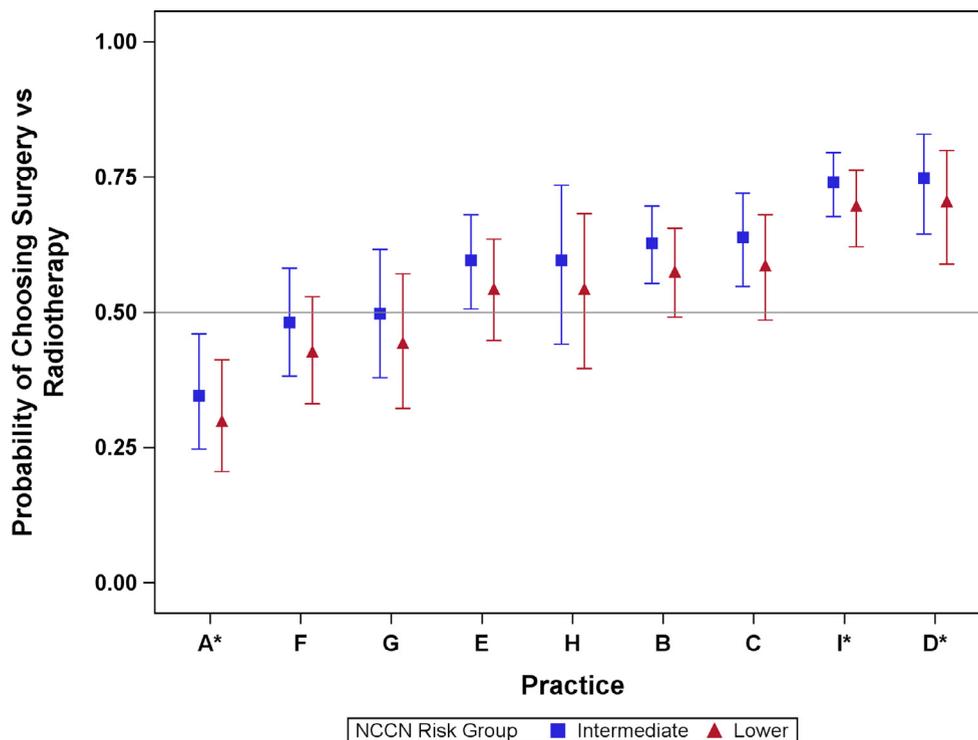


Figure 2. Practice-specific estimated probabilities for utilization of surgery vs radiotherapy as the primary therapy for men with NCCN lower and intermediate risk prostate cancer. Site B was the only site with no ownership stake in radiotherapy. (* = sites with significant variation in the baseline probability of surgery compared to radiotherapy). (Color version available online).

comorbidity, which can influence treatment choice. Biopsy type was not measured, but given the timing of this study, we don't believe the use of fusion biopsy would have been common or influenced the results.

CONCLUSION

This study demonstrates that AS was prominently utilized by urologists practicing in a large cohort of geographically diverse independent community urology group practices. Patterns of care delivery appear to be primarily consistent with clinical characteristics. Variation by practice is an opportunity for additional investigation and quality improvement efforts.

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similarly mirrored in a study from the Michigan Urological Surgery Improvement Collaborative.⁴ Although reasons for pursuing primary treatment instead of AS are not captured in this study, patient preference may be driven by factors such as anxiety, need for repeat surveillance biopsies, and distance to treatment facility, among others. While older age was predictably associated with increased use of AS, the authors surprisingly did not find a significant association of race with AS, even though African Americans have a higher risk of adverse pathologic features and progression.⁵

Considering the impact that adherence to guidelines have on healthcare delivery and reducing financial burden, this article nicely assesses the prevalent practices and adoption of AS in prostate cancer management in the community setting. The data presented reflect the practices 5+ years ago, and indeed we have witnessed a considerable shift in the evaluation of prostate cancer patients since then. In our current era, reliance on multiparametric MRI, targeted biopsies, and genomic testing has largely supplemented the traditional approach of random systematic biopsies, especially when contemplating AS in patients with presumably lower risk disease. While these approaches are increasingly becoming standard practice at many large hospitals and academic centers, such technology may not be readily available in community practices, and an updated cohort would provide interesting insight into management trends over time in light of emerging technologies.

Undoubtedly, the decision to treat or observe prostate cancer is complex and relies on an individualized approach that involves a shared decision between the provider and the patient after considering life expectancy, underlying risk factors, competing comorbidities, and patient concerns. For a field that is rapidly evolving, we must do our diligence as clinicians to stay abreast the wealth of emerging knowledge, appreciate the latest guidelines, and educate our patients in order to pursue the optimal management strategy.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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EDITORIAL COMMENT



In the treatment paradigm for prostate cancer, the pendulum has swung towards increasing use of active surveillance (AS) for lower risk disease, reflected by the most recent guidelines from the American Urological Association.¹ These recommendations are supported largely by level-1 evidence from the PIVOT and ProtecT trials, which revealed similar mortality outcomes between observation and primary treatment for patients with clinically localized disease.^{2,3} In the present study, the authors characterize the management patterns of a unique, sizable cohort of patients with very low, low, or intermediate risk prostate cancer diagnosed in one of several large community practices distributed geographically across multiple states. Although the biopsies were conducted before the most recent American Urological Association guidelines were released, the results encouragingly reveal that nearly three-fourths and half of community practices were adhering to current guideline recommendations regarding pursuit of AS as the initial treatment strategy for very low and low-risk disease, respectively. This adherence is to be applauded, as this approach theoretically is the least financially rewarding management strategy.

Undoubtedly, there are a multitude of factors that may impact treatment decisions in community practices compared to academic settings, and the authors note practice-level variation, which was

AUTHOR REPLY



The critical role of practiced based research has been articulated for at least a decade.¹ Now with intense societal and political interest in how best to control costs and improve quality in health-care, there is more need than ever to evaluate care in each of the myriad delivery models in the United States (US). Private practice, while decreasing each year as a percentage of all US health care delivery settings, remains a predominant modality and, yet, detailed evaluations of private practice care are often lacking. Thankfully this task has been made somewhat more feasible with the introduction of electronic health records, however it typically still remains cost prohibitive outside of funded evaluation efforts. To complete this work we built a novel partnership between academia and community practice, funded, in part, through an unrestricted grant from an industry partner. As the commenter points out, much work remains to be done to assess the adoption and

efficacy of new technologies being used in prostate cancer active surveillance, such as, multiparametric magnetic resonance imaging, targeted biopsy, and genetic sequencing. We have found practice-based research to be more feasible in the electronic health records era and hope to continue this work to contribute to the “real world” evidence on the use and value of new technology and innovative delivery models in this dynamic segment of healthcare.

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