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Contemporary Use of Initial Active Surveillance Among Men in Michigan with Low-risk Prostate Cancer

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Abstract

Background: Active surveillance (AS) has been proposed as an effective strategy to reduce overtreatment among men with lower risk prostate cancers. However, historical rates of initial surveillance are low (4–20%), and little is known about its application among community-based urology practices.
Objective: To describe contemporary utilization of AS among a population-based sample of men with low-risk prostate cancer.
Design, setting, and participants: We performed a prospective cohort study of men with low-risk prostate cancer managed by urologists participating in the Michigan Urological Surgery Improvement Collaborative (MUSIC).
Outcome measurements and statistical analysis: The principal outcome was receipt of AS as initial management for low-risk prostate cancer including the frequency of follow-up prostate-specific antigen (PSA) testing, prostate biopsy, and local therapy. We examined variation in the use of surveillance according to patient characteristics and across MUSIC practices. Finally, we used claims data to validate treatment classification in the MUSIC registry.
Results and limitations: We identified 682 low-risk patients from 17 MUSIC practices. Overall, 49% of men underwent initial AS. Use of initial surveillance varied widely across practices (27–80%; $p = 0.005$), even after accounting for differences in patient characteristics. Among men undergoing initial surveillance with at least 12 mo of follow-up, PSA testing was common (85%), whereas repeat biopsy was performed in only one-third of patients. There was excellent agreement between treatment assignments in the MUSIC registry and claims data ($\kappa = 0.93$). Limitations include unknown treatment for 8% of men with low-risk cancer.
Conclusions: Half of men in Michigan with low-risk prostate cancer receive initial AS. Because this proportion is much higher than reported previously, our findings suggest growing acceptance of this strategy for reducing overtreatment.
Patient summary: We examined the use of initial active surveillance for the management of men with low-risk prostate cancer across the state of Michigan. We found that initial surveillance is used much more commonly than previously reported, but the likelihood of a patient being placed on surveillance depends strongly on where he is treated.

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1. Introduction

There is substantial concern about overtreatment of men with lower risk early-stage prostate cancer [1–4]. Accordingly, many strategies have been proposed to address this issue including recommendations against the use of routine prostate-specific antigen (PSA)-based screening for early detection of prostate cancer [5], as well as efforts to unlink screening and treatment in the care of men with early-stage tumors [6,7]. Supporters of the latter approach have called for greater use of initial active surveillance (AS) with selective delayed intervention as a way for many men with low-risk cancers to avoid treatment until there is evidence of disease progression [6,8].

Although increased use of surveillance is appealing from many perspectives, existing data suggest that its utilization is uncommon (4–20%) [1,9–11], and its application by urologists in community practice remains poorly characterized. There is also skepticism that urologists can expand their use of AS, a position fortified by recent data suggesting that prostate cancer treatment decisions may be driven more by physician financial incentives than by cancer severity or patient preferences [3,12]. In addition, little is known about the implementation of surveillance outside select academic centers including how frequently patients choosing this management strategy are actually being assessed for disease progression.

In this context, we report contemporary practice patterns for the use of initial AS among patients with low-risk prostate cancer managed in the diverse academic and community practices comprising the Michigan Urological Surgery Improvement Collaborative (MUSIC). We specifically examined variation in the use of surveillance as the initial management strategy according to relevant patient and tumor characteristics, and across MUSIC practices. Additionally, we assessed the frequency of PSA testing, prostate biopsy, and local therapy among men with at least 12 mo of follow-up.

2. Material and methods

2.1. Michigan Urological Surgery Improvement Collaborative

MUSIC was established in 2011 to improve the quality and cost efficiency of prostate cancer care in the state of Michigan. With financial support provided by Blue Cross Blue Shield of Michigan (BCBSM), the collaborative now includes 42 urology practices comprising nearly 90% of urologists in the state. Each MUSIC practice obtained an exemption or approval for collaborative participation from a local institutional review board.

For all men seen in participating practices with a new prostate cancer diagnosis, trained abstractors enter a standardized set of data elements into a Web-based clinical registry including patient age, Charlson Comorbidity Index score, serial PSA results, clinical stage, biopsy Gleason score, number of positive cores, cancer-directed treatments, and follow-up laboratory results and/or biopsies. Although added more recently, patient race has not always been included in the registry.

2.2. Study population

The cohort for this analysis comprises men with a diagnosis of low-risk prostate cancer (according to the D'Amico criteria) [13] managed by urologists in MUSIC practices that were collecting data from March 2012 through August 2013. To ensure statistical reliability, we excluded from analysis 45 patients from 11 practices with <10 low-risk cases.

2.3. Primary outcome

Our outcome of interest was the use of AS as the initial management strategy among men with low-risk prostate cancer. To maximize completeness and accuracy of the data, MUSIC policy specifies that data abstractors wait 3 mo from the date of prostate cancer diagnosis before entering treatment information. Assignment of any cancer therapy, including AS, requires its explicit documentation in the medical record. For patients on AS with at least 12 mo of follow-up, we also determined the cumulative frequency of PSA testing and prostate biopsy as well as definitive local therapy.

2.4. Statistical analyses

We first generated descriptive summary statistics for the analytic sample and compared the characteristics of patients with or without treatment documented in the MUSIC registry. We then used chi-square and Fisher exact tests to compare the use of initial AS according to relevant patient and tumor characteristics, and across MUSIC practices. We then fit a multivariate regression model with practices included as a fixed effect (to account for potentially correlated data within each practice) and patient age, comorbidity, number of positive biopsy cores, and primary payer included as additional covariates. From this model, we calculated the adjusted proportion of patients undergoing AS in each practice. We also performed sensitivity analyses to assess the robustness of our findings to the exclusion criteria and to the effect of practices with the largest sample size. All statistical testing was performed using SAS v.9.0 (SAS Institute Inc., Cary, NC, USA) or Stata v.13.1 (StataCorp, College Station, TX, USA) at the 5% significance level.

2.5. Data validation

As described elsewhere [14,15], MUSIC protocol involves several steps to ensure data accuracy including development of standard operating procedures and variable definitions, abstractor training sessions, and site visits with data audits performed by the coordinating center.

For this analysis, we also used claims data from BCBSM to externally validate the treatment assigned in the MUSIC registry. Among men in the MUSIC registry with BCBSM as their primary payer, we obtained all claims data for a random 21% sample (n = 155). Guided by our prior work and the existing literature [16], we used specific Current Procedural Terminology and International Classification of Diseases, ninth revision, codes for prostate cancer treatments including prostatectomy, radiation therapy, and androgen-deprivation therapy to define claims-based algorithms for treatment assignment (Supplementary Table 1). We considered an absence of claims for local or systemic therapy as consistent with expectant management (ie, AS or watchful waiting). We then used κ statistics where appropriate to examine the level of agreement between claims-based treatment classification and primary treatment assignment in the MUSIC registry.

In addition, we obtained claims data for all men with low-risk prostate cancer managed with initial AS (according to the treatment specified in the MUSIC registry) who had BCBSM as their primary payer (n = 67). For this entire group, we again examined the concordance between treatment assignment based on claims data and the MUSIC registry.

3. Results

From March 2012 through August 2013, 2631 men with newly diagnosed prostate cancer were entered into the

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MUSIC registry. Of these, 727 were identified as having a low-risk tumor. After excluding cases from practices with <10 low-risk patients (45 patients from 11 practices), our final cohort included 682 men with low-risk prostate cancer managed by urologists in 17 MUSIC practices.

For our study cohort, the median patient age was 63 yr, and the median PSA was 5.0 ng/ml (Table 1). Treatment was documented in the MUSIC registry for 627 (91.9%) of these patients; for this cohort, the median follow-up after initiation of primary therapy was 10.8 mo. There were no significant differences in the characteristics of patients with and without treatment documented in the registry (Supplementary Table 2).

Among patients in our cohort of 627 with documented treatment, 304 (49%) underwent initial AS. This includes 15 of the 20 patients (75%) who had a second (ie, reassessment) prostate biopsy performed between their initial diagnosis and definitive treatment assignment in the MUSIC registry (Fig. 1).

Older age, Charlson Comorbidity Index score ≥2, and fewer positive biopsy cores were associated with more frequent use of AS (all p values <0.05); specifically, 54% of patients ≥70 yr, 61% of patients with a Charlson score ≥2, and 57% of patients with only one or two positive cores received initial surveillance (Fig. 2). Use of AS also varied widely across MUSIC practices, with adjusted site-specific rates ranging from 27% to 80% ($p = 0.005$) (Fig. 3). However, rates of surveillance were similar according to practice size, with 46%, 52%, and 46% undergoing initial surveillance among practices with 1–4 urologists, 5–10 urologists, and >10 urologists, respectively ($p = 0.33$).

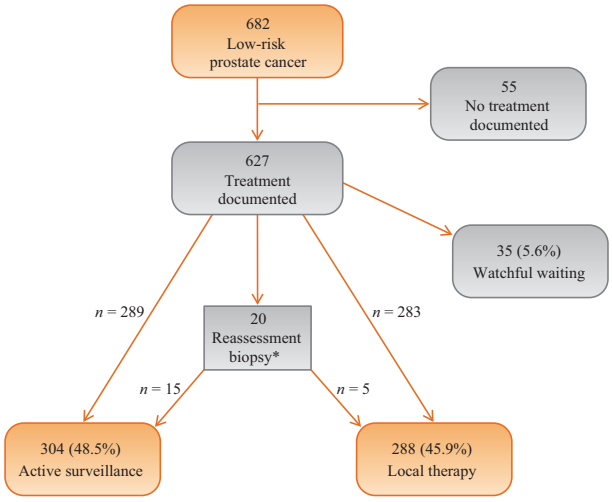

Fig. 1 – Treatment assignment for men with low-risk prostate cancer in Michigan Urological Surgery Improvement Collaborative practices. *Reassessment biopsy refers to a second biopsy performed between the date of diagnosis and the documented date of starting active surveillance.

Table 1 – Patient characteristics

Variable	Results
Total, *n* (%)	682 (100)
Age, yr, median (IQR)	63 (58–68)
<55, *n* (%)	93 (13.7)
55–69, *n* (%)	466 (68.3)
≥70, *n* (%)	123 (18.0)
Body mass index, kg/m^2, *n* (%)	
<25	123 (18.0)
25–30	315 (46.2)
≥30	221 (32.4)
Unknown	23 (3.4)
Charlson Comorbidity Index score, *n* (%)	
0	451 (66.1)
1	127 (18.6)
2+	85 (12.5)
Unknown	19 (2.8)
PSA, ng/ml, median (IQR)	5.0 (3.9–6.3)
<4, *n* (%)	176 (25.8)
4–10, *n* (%)	506 (74.2)
Clinical T stage, *n* (%)	
T1a–b	7 (1.0)
T1c	595 (87.3)
T2a	80 (11.7)
No. of positive biopsy cores, *n* (%)	
1–2	478 (70.1)
3–4	136 (19.9)
5–6	36 (5.3)
>6	25 (3.7)
Unknown	7 (1.0)
Practice size, *n* (%)	
≤4 urologists	133 (19.5)
5–10 urologists	235 (34.5)
>10 urologists	314 (46.0)

IQR = interquartile range; PSA = prostate-specific antigen.

Among 137 men followed for at least 12 mo after initiating surveillance, PSA testing was extremely common, whereas prostate biopsy was performed in only one-third of patients (Fig. 4). For the 18 patients (13%) who received subsequent local therapy, all had at least one repeat PSA, and 61% had a repeat biopsy before proceeding with treatment.

3.1. *Sensitivity analyses*

To ensure that our exclusion criteria had not biased these results, we assessed the proportion of men who were placed on AS from the 11 practices with <10 patients with low-risk prostate cancer. Among these 45 cases, 36 (80%) had treatment documented in the MUSIC registry. Of these, 12 (33%) underwent initial AS. If these cases were included in our overall analysis, the overall rate of surveillance would be similar at 48% (316 of 663).

To assess whether practices with the largest sample size were driving our results, we repeated our analysis after excluding the three practices with the largest patient volumes ($n = 164$, 87, and 83 low-risk patients, respectively). This resulted in little change in the overall proportion of patients undergoing initial surveillance (49%, 161 of 328).

3.2. *Data validation*

Among the validation sample of 155 men, 29 did not have a treatment recorded in the MUSIC registry. For the remaining 126 cases (81%), we used Cohen κ statistics to examine the level of agreement between claims-based treatment

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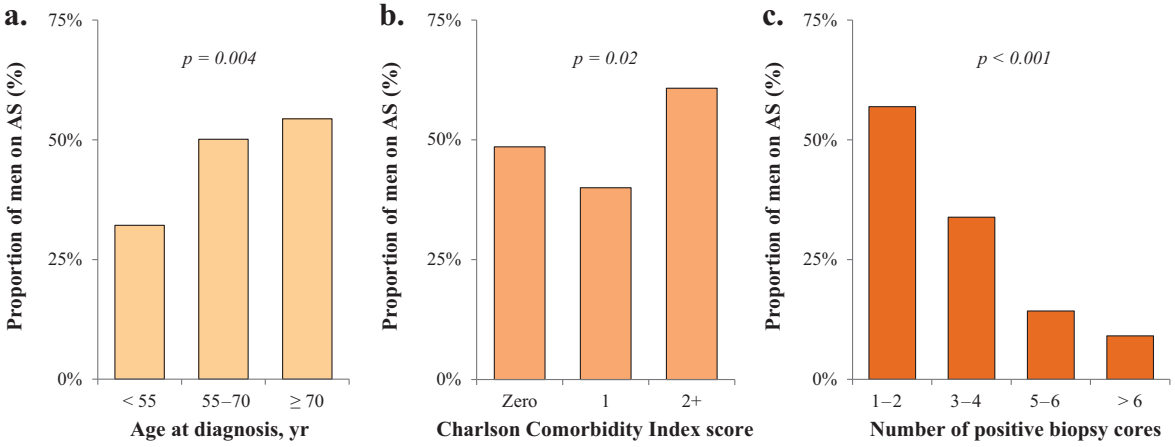

Fig. 2 – Proportion of men with low-risk prostate cancer undergoing initial active surveillance according to (a) age at diagnosis, (b) Charlson Comorbidity Index score, and (c) number of positive cores.
AS = active surveillance.

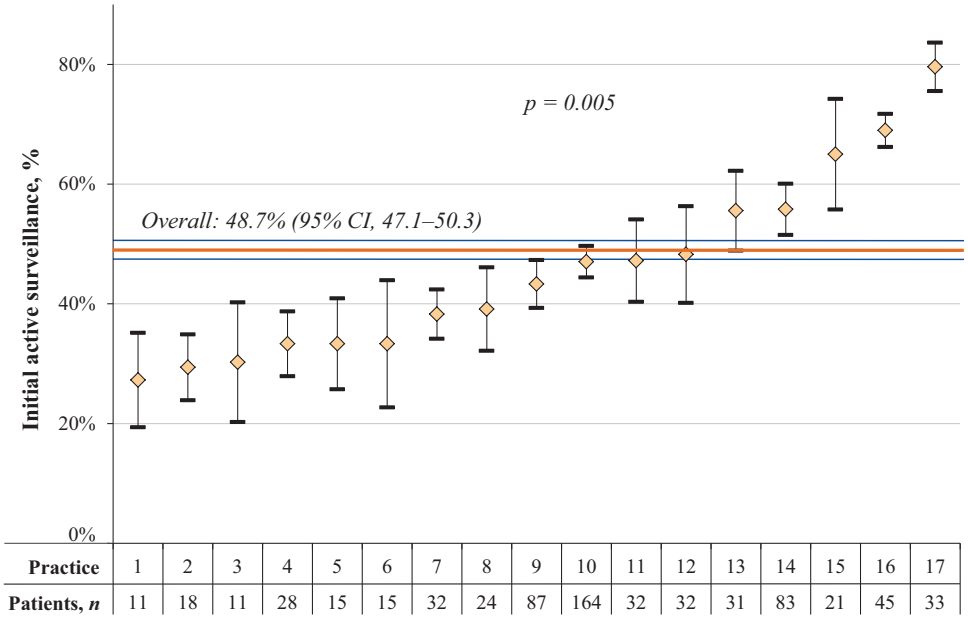

Fig. 3 – Adjusted likelihood of active surveillance for men with low-risk prostate cancer, stratified by Michigan Urological Surgery Improvement Collaborative practices. Model adjusts for age, Charlson Comorbidity Index score, number of positive cores, and primary payer.
CI = confidence interval.

Table 2 – Comparison of treatment assignment based on the Michigan Urological Surgery Improvement Collaborative registry and claims data (κ = 0.93)

	MUSIC registry			
Claims data	Surgery	Radiation therapy	ADT	Expectant management*
Surgery†	75	1	0	0
Radiation therapy‡	0	18	0	1
ADT§	0	0	3	0
No treatment claims	2	1	0	25

ADT = androgen deprivation therapy; MUSIC = Michigan Urological Surgery Improvement Collaborative.
Local therapy consists of surgery, radiation therapy, or cryotherapy. Treatment-specific analyses can be found in Supplementary Table 3.
* In MUSIC registry: active surveillance or watchful waiting.
† Radical retropubic prostatectomy, robot-assisted laparoscopic prostatectomy, or radical perineal prostatectomy.
‡ External-beam radiation therapy, intensity-modulated radiation therapy, or brachytherapy.
§ ADT as primary treatment.

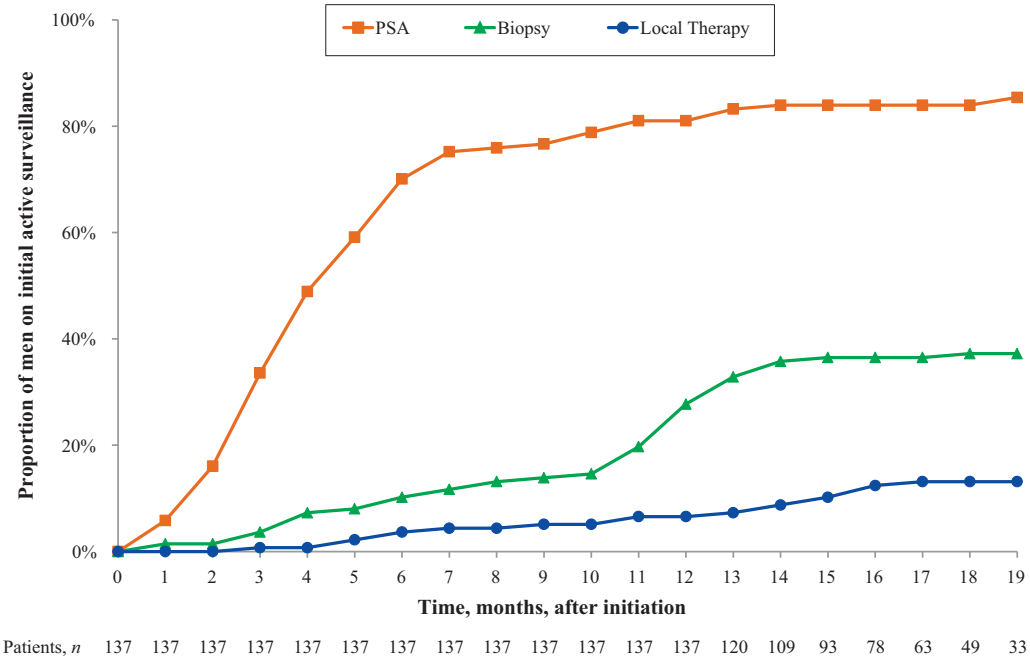

Fig. 4 – Cumulative incidence of follow-up prostate-specific antigen (PSA) testing, prostate biopsy, and definitive local therapy. Among 137 men with at least 12 mo of follow-up after initiating active surveillance for low-risk prostate cancer, 85.4% had at least one PSA, 37.2% underwent a repeat prostate biopsy, and 13.1% transitioned to local therapy.
PSA = prostate-specific antigen.

classification and primary treatment assignment in the MUSIC registry. As illustrated in Table 2, we observed excellent concordance ($\kappa = 0.93$) between primary treatment assignment from the two data sources.

Among the 67 men with low-risk prostate cancer managed with AS who had BCBSM as their primary payer, 57 (85%) had no claims data indicating local or systemic prostate cancer therapy. Seven patients (10%) had evidence for treatment based on claims data that matched the secondary treatment recorded in the MUSIC registry (ie, these patients went on to definitive local therapy after a period of initial surveillance). Of the remaining three patients, two (3%) had claims for treatment performed within the 3-mo lag time before data entry into the registry, and one (<2%) had claims for a treatment that was not recorded in the registry; investigating this case we learned that the patient received treatment at a practice outside MUSIC.

4. Discussion

In this analysis of contemporary data from a large sample of diverse community and academic practices in Michigan, we observed that nearly 50% of men with low-risk prostate cancer undergo initial AS rather than definitive local therapy. Older men and those with the greatest burden of comorbid conditions are most likely to select this expectant strategy. Although the overall rate of surveillance is substantively higher than reported in previous population-based data, its application varies widely across urology practices. Once on surveillance, most men have repeat PSA testing; however, only one in three patients received a repeat prostate biopsy in the first 12 mo of follow-up.

Because the survival benefits of local therapy may be limited to select patients [17,18], many now view surveillance as the preferred initial treatment option for men with low-risk prostate cancer [6]. Nevertheless, existing data suggest that this approach is used in <20% of these patients [1,9–11]. Significantly, our results indicate a much greater application of initial surveillance in Michigan, with half of low-risk patients now selecting this expectant management option. Our validation steps underscore the accuracy of this estimate, and this finding suggests a significant transition in patterns of care for men with low-risk tumors.

Our findings should be considered in the context of several limitations. First, our ability to validate treatment with claims data was limited to patients with BCBSM. Nonetheless, BCBSM is the major payer for younger non-Medicare beneficiaries in Michigan, the patients for whom concerns about overestimating use of AS would be greatest. Second, we were unable to determine treatment for 8% of men with low-risk disease. However, there were no differences in measurable patient characteristics between this group and patients with known treatment, and it seems highly unlikely that these men systematically received local therapy that was not identifiable by either data abstractors or medical claims. Finally, the degree to which AS actually reduces overtreatment ultimately depends on its long-term implementation among men without evidence of disease progression. As such, longer follow-up is needed to confirm the durability and outcomes of surveillance in this population.

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These limitations notwithstanding, our data have significant implications for the care of men with early-stage prostate cancer. The finding that half of men in Michigan with low-risk prostate cancer, even as defined by the relatively broad D'Amico criteria, are undergoing initial surveillance provides empirical support for a growing acceptance of this strategy for reducing overtreatment among both urologists and increasingly well-informed patients seeking treatment for early-stage prostate cancer. This perspective is further supported by the fact that these data represent practice patterns before the implementation of any specific MUSIC initiatives focused on AS or other treatment decisions. At the same time, however, the substantial variation across practices highlights the need for future work aimed at better understanding the patient, disease, and provider factors that drive recommendations for, and acceptance of, initial surveillance.

The data on PSA testing and follow-up biopsy are also consequential. Given that periodic reassessment of disease risk to identify patients who should transition to local therapy represents a central tenet of AS, the high frequency of any follow-up testing during this interval further validates that these men are on surveillance rather than watchful waiting. At the same time, however, our finding that repeat biopsy was performed for only one in three men on AS for >12 mo reflects the many potential impediments to achieving such stringent follow-up in real-world practice, and it highlights the need for standardized, but still pragmatic, surveillance protocols [19,20]. In addition to PSA testing and repeat biopsy, such pathways may evolve to include magnetic resonance imaging, genomic biomarkers, or other emerging methods for assessing tumor progression [21,22].

5. Conclusions

Moving forward, MUSIC's distinct infrastructure, including the discourse at our tri-annual collaborative-wide meetings and local leadership by clinical champions in each practice, will allow us to act on these data by developing and implementing quality improvement initiatives aimed at addressing these pivotal issues in the care of men with low-risk prostate cancer. Ultimately, the impact of such work will hinge on whether or not greater adoption and better implementation of AS delivers on the promise of maintaining population declines in prostate cancer–specific mortality while reducing the burden of treatment-related morbidity.

Author contributions: Paul R. Womble had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Womble, Lane, Montie, Miller.
Acquisition of data: Linsell, Ye, Womble.
Analysis and interpretation of data: Womble, Miller, Montie, Ye, Lane.
Drafting of the manuscript: Womble, Montie, Lane, Miller.
Critical revision of the manuscript for important intellectual content: Womble, Montie, Lane, Miller.
Statistical analysis: Ye, Womble.
Obtaining funding: Linsell, Montie, Miller.
Administrative, technical, or material support: Linsell.
Supervision: Miller, Montie, Lane.
Other (specify): None.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eururo.2014.08.024.

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