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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