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Prostate Cancer

Understanding the Use of Prostate Biopsy Among Men with Limited Life Expectancy in a Statewide Quality Improvement Collaborative

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Abstract

Background: The potential harms of a prostate cancer (PCa) diagnosis may outweigh its benefits in elderly men.
Objective: To assess the use of prostate biopsy in men with limited life expectancy (LE) within the practices comprising the Michigan Urological Surgery Improvement Collaborative (MUSIC).
Design, setting, and participants: MUSIC is a consortium of 42 practices and nearly 85% of the urologists in Michigan. From July 2013 to October 2014, clinical data were collected prospectively for all men undergoing prostate biopsy.
Outcome measurements and statistical analysis: We calculated comorbidity-adjusted LE in men aged ≥66 yr and identified men with <10 yr LE (limited LE) undergoing a first biopsy. Our LE calculator was not designed for men aged <66 yr; thus these men were excluded. Multivariable models estimated the proportion of all biopsies performed for men with limited LE in each MUSIC practice, adjusting for differences in patient characteristics. We also evaluated what treatments, if any, these patients received.
Results and limitations: Among 3035 men aged ≥66 yr undergoing initial prostate biopsy, 60% had none of the measured comorbidities. Overall, 547 men (18%) had limited LE. Compared with men with a longer LE, these men had significantly higher prostate-specific antigen levels and abnormal digital rectal examination findings. The adjusted proportion of biopsies performed for men with limited LE ranged from 3.8% to 39% across MUSIC practices ($p < 0.001$). PCa was diagnosed in 69% of men with limited LE; among this group, 74% received any active treatment. Of these men, 46% had high-grade cancer (Gleason score 8–10).
Conclusions: Among a large and diverse group of urology practices, nearly 20% of prostate biopsies are performed in men with limited LE. These data provide useful context for quality improvement efforts aimed at optimizing patient selection for prostate biopsy.
Patient summary: In this report, nearly 2 of every 10 men undergoing prostate biopsy had a life expectancy (LE) <10 yr. Implementing LE calculators in clinical practice may help refine patient selection for prostate biopsy.
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1. Introduction

Over the past two decades, the introduction of prostate-specific antigen (PSA) testing has led to a substantial increase in the number of men recommended for prostate biopsy. Despite being office based, this procedure carries a significant risk of complications and has a non-negligible cost [1,2]. Complications after prostate biopsy include hematuria, rectal bleeding, hematospermia, urinary tract infection, and urinary retention. A 2014 study showed that almost 72% of the costs of PSA screening are derived from prostate biopsy and/or its complications [2].

Because many patients diagnosed with prostate cancer (PCa) in the PSA era have relatively indolent tumors with a protracted natural history [3–5], many believe that offering prostate biopsy to men with limited life expectancy (LE) exposes them to the risks of prostate biopsy and possible overtreatment of PCa without offering a clear survival benefit. For this reason, guidelines now recommend against PCa screening (and thus prostate biopsy) in men with <10 yr of LE [6–8]. One drawback of this strategy is that a clinician's estimate of LE may be inaccurate. In this setting, the nonrecommended use of prostate biopsy in men with limited LE may be a potential focus of quality improvement. However, a necessary first step is to better define the actual prevalence of prostate biopsies among men with limited LE.

To address this knowledge gap, we examined the proportion of prostate biopsies performed in men with a LE <10 yr among the diverse community and academic practices comprising the Michigan Urological Surgery Improvement Collaborative (MUSIC).

2. Methods

2.1. Michigan Urological Surgery Improvement Collaborative

A comprehensive description of MUSIC was published previously [9]. The aim of the collaborative is to improve the quality of PCa care in Michigan. MUSIC is funded by Blue Cross Blue Shield of Michigan and includes 42 urology practices comprising nearly 85% of the urologists in the state. Each participating practice obtained an exemption or approval for participation from its local institutional review board. In each practice, abstractors prospectively enter a standardized set of data elements into a secure online-based clinical registry for all patients (regardless of payer) undergoing prostate biopsy. One urologist per practice serves as the clinical champion with responsibilities that include oversight of local data collection and leadership around local implementation of quality improvement activities. The MUSIC coordinating center is responsible for overall administration and management of collaborative activities. In July 2013, the MUSIC registry was expanded to collect comorbidity data on 19 conditions for all patients undergoing prostate biopsy (Supplement 1).

2.2. Study population

Our cohort consisted of 3035 men undergoing first-time prostate biopsy within MUSIC practices from July 2013 through October 2014, with comorbidity data collected prospectively. For the purpose of this study, patients aged <66 yr were excluded. This was done for two reasons. First, to calculate LE, we used a comorbidity-adjusted method published in 2013 [10] that was specifically developed in persons aged ≥66 yr. Second, patients aged <66 yr are less likely to have a limited LE.

2.3. Outcomes

Our main outcome was the use of prostate biopsy in men with a calculated LE <10 yr. In sensitivity analyses, we modified our outcomes to assess prostate biopsy using alternative definitions of LE and/or combining these with PSA values including (1) use of biopsy in men with calculated LE <8 yr, (2) use of biopsy in men with calculated LE <10 yr and PSA <10 ng/ml, and (3) use of biopsy in men with calculated LE <10 yr and PSA <25 ng/ml.

LE was calculated based on life tables developed by Cho et al [10]. Besides accounting for conventional variables such as age, sex, and race, these tables also incorporate comorbidity status, which is increasingly recognized as an important predictor of overall survival [11]. These tables were based on individuals without a history of cancer and were designed specifically to help improve screening strategies. Supplement 2 provides a more detailed description of these tables. Finally, to better understand the consequences of PCa diagnosis in patients with limited LE, we also evaluated what PCa treatments, if any, these patients received.

2.4. Patient and practice characteristics

For each patient, the following variables were extracted: age at biopsy, Charlson Comorbidity Index (CCI), race (white vs black vs others), family history of PCa (negative vs positive vs unknown), body mass index (BMI), PSA value, digital rectal examination (DRE) (abnormal vs normal vs unknown), insurance category (private vs public [Medicare, Medicaid] vs uninsured vs unknown), and practice volume (defined as the number of biopsies performed by each specific practice within the study period). The latter variable was categorized into quartiles.

2.5. Statistical analyses

To ensure statistical reliability, we excluded from our analysis the practices with <10 biopsies. Descriptive statistics of categorical variables consist of frequencies and proportions. Means, medians, and interquartile ranges (IQRs) are reported for continuously variables. The chi-square test and Mann-Whitney tests were used to compare the statistical significance of differences in proportions and medians, respectively. We also fit univariable and multivariable logistic regression models to examine the association between measured patient characteristics and the main outcome: use of prostate biopsy in patients with a calculated LE <10 yr. The multivariable model was also used to calculate the adjusted proportion of biopsies in each MUSIC practice that were performed for patients with an LE <10 yr. All statistical testing was performed using SAS software v.9.0 (SAS Institute Inc., Cary, NC, USA) or Stata software v.13.1 (StataCorp, College Station, TX, USA) at the 5% significance level.

3. Results

Table 1 summarizes the demographic characteristics of 3035 men aged ≥66 yr undergoing an initial prostate biopsy within MUSIC practices. The median age was 73.9 yr (IQR: 69.1–78.3 yr), and the median BMI was 27.9 (IQR: 25.1–31.0). It is noteworthy that 8.1% of patients (n = 248) who underwent an initial biopsy were aged ≥80 yr. Most patients were white (78.7%), had a CCI 0 (60.3%), and reported a negative PCa family history (70.3%). The median

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