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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

Table 1 – Characteristics of men undergoing prostate biopsy in Michigan Urological Surgery Improvement Collaborative practices, July 2013–October 2014

Variables	Overall n = 3035 (100%)	Men with <10 yr life expectancy n = 547 (18%)	Men with ≥10 yr life expectancy n = 2488 (82%)	p value
Age, yr				
Median	73.9	77.4	70.5	<0.001
IQR	69.1–78.3	70.1–82.9	68.0–73.6	
Age, yr, n (%)				
66–70	1280 (42.2)	136 (24.9)	1144 (46)	<0.001
>70–75	1018 (33.5)	105 (19.2)	913 (36.7)	
>75–80	489 (16.1)	58 (10.6)	431 (17.3)	
>80–85	166 (5.5)	166 (30.3)	0 (0)	
>85	82 (2.7)	82 (15)	0 (0)	
Charlson Comorbidity Index score, n (%)				
0	1830 (60.3)	126 (23)	1704 (68.5)	<0.001
1	909 (29.9)	199 (36.4)	710 (28.5)	
≥2	296 (9.8)	222 (40.6)	74 (3)	
Race/ethnicity, n (%)				
White	2388 (78.7)	425 (77.7)	1963 (78.9)	0.4
Black	330 (10.9)	68 (12.4)	262 (10.5)	
Other	317 (10.4)	54 (9.9)	263 (10.6)	
Family history, n (%)				
Negative	2133 (70.3)	384 (70.2)	1749 (70.3)	<0.001*
Positive	639 (21.1)	90 (16.5)	549 (22.1)	
Unknown	263 (8.7)	73 (13.4)	190 (7.6)	
Body mass index, n (%)				
<25	603 (19.9)	137 (25.1)	466 (18.7)	<0.001*
25–30	1337 (44.1)	239 (43.7)	1098 (44.1)	
>30	992 (32.7)	152 (27.8)	840 (33.8)	
Unknown	103 (3.4)	19 (3.5)	84 (3.4)	
Prostate-specific antigen, ng/ml, n (%)				
<4	530 (17.5)	78 (14.3)	452 (18.2)	<0.001*
4–10	1832 (60.4)	266 (48.6)	1566 (62.9)	
>10	656 (21.6)	198 (36.2)	458 (18.4)	
Unknown	17 (0.6)	5 (0.9)	12 (0.5)	
Digital rectal examination, n (%)				
Abnormal	709 (23.4)	154 (28.2)	555 (22.3)	0.006*
Normal	1923 (63.4)	329 (60.5)	1594 (64.1)	
Unknown	403 (13.3)	64 (11.7)	339 (13.6)	
Insurance category, n (%)				
Private	758 (25)	130 (23.8)	628 (25.2)	0.5†
Public	2264 (74.6)	415 (75.9)	1849 (74.3)	
Uninsured	7 (0.2)	2 (0.4)	5 (0.2)	
Unknown	6 (0.2)	0 (0)	6 (0.2)	
Practice volume quartile, n (%)				
First	733 (24.2)	145 (26.5)	588 (23.6)	0.01
Second	801 (26.4)	119 (21.8)	682 (27.4)	
Third	608 (20.0)	101 (18.5)	507 (20.4)	
Fourth	893 (29.4)	182 (33.2)	711 (28.6)	

IQR = interquartile range.

* The p values are based exclusively on known data.

PSA value was 6.8 ng/ml (IQR: 4.6–10.9 ng/ml), and most patients had a negative DRE (63.4%).

Among men undergoing initial biopsy, 547 (18%) had a calculated LE <10 yr. These men were older (median: 77.4 vs 70.5 yr; $p < 0.001$), with more comorbid conditions (CCI ≥2: 40.6% vs 3%; $p < 0.001$), lower BMIs (27.5 vs 28.2; $p = 0.001$), and more frequently treatment in higher volume practices (fourth quartile: 33.2% vs 28.6%; $p = 0.01$) than men with ≥10 yr of LE. Likewise, men with limited LE had higher PSA values (median: 7.6 vs 5.9 ng/ml; $p < 0.001$) and more frequently had abnormal DREs (28.2% vs 22.3%; $p = 0.006$). Conversely, men with limited LE who underwent prostate biopsy less frequently reported a positive PCa family history (16.5% vs 22.1%; $p < 0.001$) in comparison

with their counterparts with a LE ≥10 yr. **Figure 1** compares the adjusted proportion of all prostate biopsies performed for men with an estimated LE <10 yr. This ranged from 3.8% to 39% ($p < 0.001$) across 32 MUSIC practices, with a mean of 17.5% (95% confidence interval [CI], 16.1–18.9). The rates of biopsy vary if alternative definitions of LE and/or combining LE with specific PSA cut-off values are used, as noted in Supplementary Figure 1–3.

Table 2 presents results from logistic regression models used to estimate associations between patient and practice characteristics and the likelihood of performing biopsies for patients with LE <10 yr. On multivariable analysis, an abnormal DRE (odds ratio: 1.38; 95% CI, 1.11–1.72; $p = 0.003$) was associated with a higher probability of

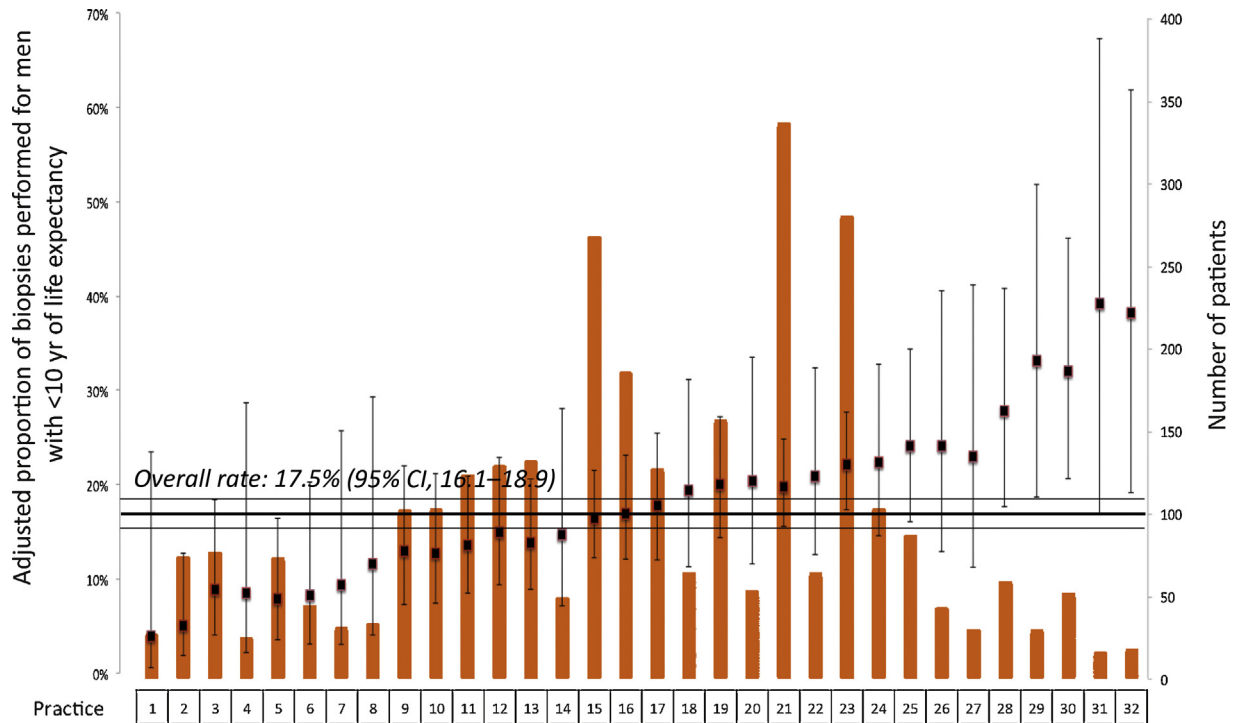


Fig. 1 – Adjusted proportion of all prostate biopsies performed for men with an estimated life expectancy <10 yr across 32 Michigan Urological Surgery Improvement Collaborative practices (with number of patients in each practice biopsied denoted). Model adjusts for race, body mass index, prostate-specific antigen value, digital rectal examination findings, family history of prostate cancer, primary payer, and practice volume.

having a limited LE at first-time biopsy. Conversely, a higher BMI was associated with a lower likelihood of getting a prostate biopsy in men with limited LE. Notably, race, PSA value, insurance status, family history of PCa, and practice volume were not independent predictors of limited LE at first-time biopsy.

Among men with limited LE who underwent biopsy, 376 men (69%; 95% CI, 64.7–72.7) were diagnosed with PCa. Among this group, biopsy Gleason score distribution was 2–6, 7, and 8–10 in 19% (95% CI, 15.3–23.5), 44% (95% CI, 38.8–49.2), and 37% (95% CI, 31.5–41.5), respectively. Most of these patients (74%; 95% CI, 69.4–78.6) received active

Table 2 – Association between patient characteristics and likelihood of prostate biopsy among men with life expectancy <10 yr

Variables	Bivariate analysis		Multivariate analysis	
	OR (95% CI)	p value	OR (95% CI)	p value
Race		0.4		0.5
White	[Ref.]	–	[Ref.]	–
Black	1.19 (0.90–1.59)	0.2	1.10 (0.80–1.51)	0.5
Others	0.94 (0.69–1.29)	0.7	0.83 (0.58–1.20)	0.3
Family history		<0.001		0.01
Negative	[Ref.]	–	[Ref.]	–
Positive	0.74 (0.58–0.95)	0.02	0.80 (0.61–1.05)	0.1
Unknown	1.75 (1.30–2.34)	<0.001	1.51 (1.05–2.18)	0.02
Body mass index, kg/m ²		0.001		<0.001
<25	[Ref.]	–	[Ref.]	–
25–30	0.74 (0.58–0.93)	0.01	0.67 (0.52–0.87)	0.002
>30	0.61 (0.47–0.79)	<0.001	0.57 (0.43–0.76)	<0.001
Prostate-specific antigen, ng/ml	1.00 (1.00–1.00)	0.4	1.00 (0.99–1.00)	0.9
Digital rectal examination				
Normal	[Ref.]	–	[Ref.]	–
Abnormal	1.34 (1.08–1.66)	0.006	1.38 (1.11–1.72)	0.003
Insurance category		0.6		0.8
Private	[Ref.]	–	[Ref.]	–
Public	0.92 (0.74–1.14)	0.4	0.91 (0.72–1.16)	0.4
Uninsured	0.51 (0.09–2.68)	0.4	0.73 (0.07–7.3)	0.8
Practice volume quartile	1.00 (1.00–1.00)	0.07	1.00 (1.00–1.00)	0.2

CI = confidence interval; OR = odds ratio; Ref. = reference category.

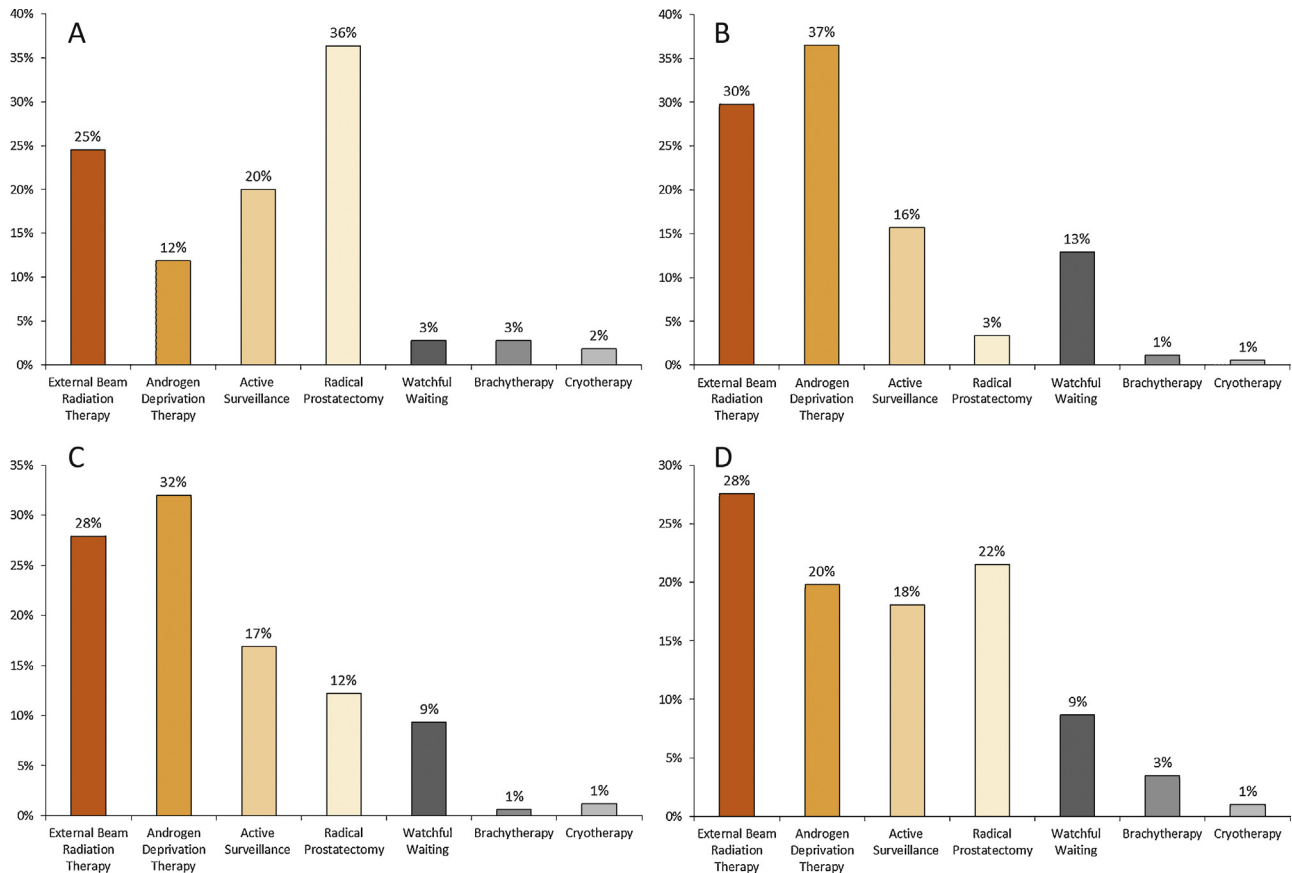


Fig. 2 – Treatment patterns in men with a calculated life expectancy <10 yr diagnosed with prostate cancer after undergoing prostate biopsy within the Michigan Urological Surgery Improvement Collaborative stratified according to age and comorbidity: (A) age ≤75 yr, (B) age >75 yr, (C) Charlson Comorbidity Index (CCI) 0–1, and (D) CCI ≥2.

treatment that consisted of radiotherapy (external beam or brachytherapy), surgery, androgen deprivation therapy (ADT), and cryotherapy. Radiation therapy was the most frequent treatment (28%); radical prostatectomy was performed in 16%. Gleason score distribution among those receiving active treatment was 5.8%, 48.1%, and 46.1% for Gleason 2–6, 7, and 8–10, respectively, and metastatic disease was identified in 9.2% of patients. **Figure 2** illustrates the management in these patients in more detail, stratified according to their age (≤75 and >75 yr) and CCI (0–1 and ≥2).

Supplementary Table 1 offers a further analysis comparing characteristics of patients diagnosed with PCa with limited LE against those patients with a longer LE. Among those with positive biopsies, men with a limited LE had significantly higher PSA values and abnormal DRE findings. In particular men with limited LE had at least twice the rate of PSA values >10 ng/mL at the time of biopsy.

4. Discussion

We found that among men aged >66 yr undergoing initial prostate biopsy, nearly 20% had a calculated LE <10 yr. Despite adjusting for patient variables, the proportion of patients with a limited LE undergoing a prostate biopsy varied depending on the practice at which the patient was

treated. Once diagnosed with PCa, most men with limited LE had higher grade cancers (ie, Gleason score 7–10) and received immediate treatment with radiation therapy, ADT, or surgery.

Our study is novel in that previous reports assessing LE in men undergoing prostate biopsy based estimates on age and/or other demographic characteristics [12]. Using age alone might be misleading because individuals of the same age can have different LEs based on their general health status [10,11,13]. This is noted in our study in which the vast majority of men with limited LE undergoing radical prostatectomy were aged ≤75 yr, yet this same group had men with greater comorbidity. Also, we calculated LE estimates based on recently published comorbidity-adjusted life tables specifically designed for estimating this in individuals undergoing cancer screening [10]. Whereas groups such as the Prostate Cancer Outcomes Study [14] and Cancer of the Prostate Strategic Urologic Research Endeavor [15] have also assessed LE on men diagnosed with PCa, very few have tried to understand this practice in all patients presenting for biopsy. Many studies examining the effect of cancer on patient mortality are restricted to the excess mortality attributable to cancer [16]. In this regard, our study serves to provide data for quality improvement efforts aimed at optimizing patient selection for prostate biopsy.

Wasson et al examined a historic cohort of patients within the 5% of Medicare beneficiaries receiving prostate biopsy between 1993 and 1997 [12]. They found that 22% of these patients who underwent biopsies had a limited LE. Men aged ≥ 80 yr and those aged 65–79 yr with any comorbid condition according to the CCI were considered to have a limited LE (ie, < 10 yr), whereas everybody else was considered to have an LE ≥ 10 yr. Although there are several methodological differences between this report and our study, which uses a contemporary cohort in an era where more caution is placed on overdiagnosis and treatment, it is interesting to observe that the rate of prostate biopsy in this group of men appears stable over time.

This finding might be attributed, at least partially, to the challenges associated with estimating LE [17–19]. Despite current recommendations to incorporate LE in clinical decision making for PCa care [6–8], many urologists do not formally assess this measure, which might be attributed to several factors. LE calculators can be cumbersome and time consuming to use during everyday clinical practice. Also, many of these tools require a large amount of clinical information that is not routinely available to urologists. Despite the availability of multiple methods for calculating LE, most lack external validation and/or show suboptimal performance [16,20].

Thus these tools are not widely accepted. Rather than LE, patient clinical characteristics appear to drive the decision to perform prostate biopsy. Our results confirm that in men with limited LE, the likelihood of undergoing a prostate biopsy was greater when PSA value was higher at presentation and/or the DRE was abnormal. Although it is understandable how such clinical characteristics might lower the threshold to perform a prostate biopsy that may be clinically appropriate, level 1 evidence has failed to demonstrate a survival benefit in patients with limited LE who are actively treated, regardless of tumor characteristics [21,22]. Nonetheless, many urologists may consider treatment to prevent the morbidity of metastatic disease and the potential impact of missing possibly lethal cancer by triaging care based on LE at the time of biopsy decision, rather than at the time of treatment, an aspect of care that warrants further investigation. Within MUSIC, we are in the process of implementing a prostate biopsy cancer risk calculator that will help identify patients at greater risk of high-grade tumors.

In our report, 74% of men with a limited LE and a PCa diagnosis received active treatment. This is in keeping with a report based on a recent Surveillance Epidemiology and End Results–Medicare report showing an overall active treatment rate of 82% in men aged ≥ 66 yr [23]. Using the same database, Daskivich et al [24] also showed that among men with an LE < 10 yr, procedural treatment (surgery, radiation, or brachytherapy) occurred in 68% of men aged 66–69 yr, 69% of men aged 70–74 yr, 57% of men aged 75–79 yr, and 24% of men aged ≥ 80 yr.

The limitations of our study include the use of an LE calculation method that is not applicable to men aged < 66 yr [10]. The method of Cho et al [10] may not be sufficient to address the overall fitness of a patient. For example, the

International Society of Geriatric Oncology proposed other instruments, such as the G8 screening tool [25], dependence status, nutritional status, and neuropsychological screening along with a comorbidity assessment to decide the fitness of older patients [26]. Although the method of Cho et al [10] is one way of calculating LE, several other analyses in the literature have assessed LE in PCa patients [16], and using alternative methods and/or definitions of limited LE might provide different results, as shown in our sensitivity analyses.

Many other factors inform decision making to proceed to prostate biopsy including but not limited to patient anxiety, fear of cancer, and personal preferences; we were not able to measure and account for these influences. Our study design did not allow us to examine the impact of these biopsies on overall survival. Previous population-based studies and prospective trials have shown that the benefit of active treatment in elderly and/or sick patients is limited [21,27]. Nonetheless, men with limited LE who harbor high-risk tumors may warrant treatment in some instances to avoid complications associated with advanced disease.

Although our observations are limited to practice within a single state, our prospective cohort consists of all payer data from both large and small urology practices, and it likely reflects practice throughout the country. Our registry does not capture the number of men in whom prostate biopsy may have been indicated but was not performed because of limited LE. The influence of practice/physician factors such as experience or subspecialty focus is not captured in our registry. Finally, we did not assess the impact of LE on patients undergoing a repeat biopsy in this study. However, in a separate analysis, we found that the rate of rebiopsy is low (5.9%) and that LE did not influence the likelihood of a rebiopsy.

When considering prostate biopsy indications, the risks and benefits should be tailored to the patient's specific health status and preferences. Efforts such as the "Too Much Medicine" and "Choosing Wisely" campaigns have sought to limit the overuse of procedures and treatment by encouraging patients and providers to discuss the appropriateness of care when the value of service might be low [28]. The use of prostate biopsy in individuals with a limited LE may expose some men to a procedure with potential morbidity, without offering a significant survival benefit. Such biopsies may also contribute to the growing problem of increased antibiotic resistance [29–31]. The latter represents an important issue, especially for men with multiple health problems.

The rate of biopsies in men with a limited LE varied largely depending on the practice. Although treatment variation in PCa care is an inevitable part of the current health care landscape, efforts are needed to address unwarranted variation [32]. We have previously demonstrated variation in PCa care related to prostate biopsy-related infection rates and utilization of active surveillance [9,33]. Practices with high utilization of biopsies in men with a limited LE may benefit from quality improvement initiatives that seek to educate providers on optimal patient selection. A previous study demonstrated that quality

improvement efforts that incorporate a quality measure, such as the incidence of nonrecommended prostate biopsy, are effective in promoting utilization of appropriate care [34]. One way to do this might be to provide practices with pragmatic and efficient methods for calculating LE in clinical practice. We are currently examining the feasibility of a standardized LE calculator for use in MUSIC practices, to aid at time of biopsy selection and also to help with downstream shared decision making regarding appropriate treatment.

5. Conclusions

Nearly 20% of men aged >66 yr undergoing prostate biopsy in MUSIC practices have a limited LE. Realizing that the discussion about the risk of PCa in patients is complex and will need to be informed by patient preferences, implementing LE calculators in clinical practice may be a useful tool for further refining the selection of patients for prostate biopsy.

Author contributions: Khurshid Ghani 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: Abdollah, Ghani, Peabody.

Acquisition of data: Ghani, Miller, Linsell.

Analysis and interpretation of data: Abdollah, Ye, Ghani.

Drafting of the manuscript: Abdollah, Ghani.

Critical revision of the manuscript for important intellectual content: Miller, Peabody, Montie.

Statistical analysis: Ye.

Obtaining funding: Miller, Montie.

Administrative, technical, or material support: Linsell.

Supervision: Ghani.

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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.2016.03.054>.

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