

UROLOGIC ONCOLOGY

Urologic Oncology: Seminars and Original Investigations ■ (2017) ■■■-■■■

Original article

Outcomes of men on active surveillance for low-risk prostate cancer at a safety-net hospital

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Received 27 April 2017; received in revised form 6 June 2017; accepted 1 July 2017

Purpose: To characterize demographic, disease, and cancer outcomes of men on active surveillance (AS) at a safety-net hospital and characterize those who were lost to follow-up (LTFU).

Methods: From January 2004 to November 2014, 104 men with low-risk prostate cancer (PCa) were followed with AS at Zuckerberg San Francisco General Hospital (ZSFG). Criteria for AS have evolved over time; however, patients with diagnostic prostate-specific antigen (PSA) 10 ng/mL or less, clinical stage T1/2, biopsy Gleason score 3 + 3 or 3 + 4, 33% or fewer positive cores, and 50% or less tumor in any single core were potentially eligible for AS. Men were longitudinally followed with a PSA or digital rectal examination or both every 3 to 6 months, and repeat prostate biopsy every 1 to 2 years. Clinical staging and grading were based on a physical examination and at least a 12-core biopsy, respectively. LTFU was defined as failure to successfully contact patients with 3 phone calls or any urology visit recorded within 18 months from a prior visit or biopsy. A secondary chart review was performed using the electronic medical record at ZSFG as well as EPIC Systems CareEverywhere which allows access to select non-ZSFG institutions to confirm that patients were truly LTFU.

Results: Among the 104 men on AS at ZSFG, the median age at diagnosis of PCa was 61.5 years (range: 44–81). The median follow-up period was 29 months (range: 0–186 months) during which 18 (17.3%) men were LTFU and 48 (46%) remained on surveillance. Men underwent a median of 7 (1–21) serum PSA measurements and an average of 2 prostate biopsies (1–5). In total, 22 (20.6%) men had definitive treatment with the median time from diagnosis to active treatment being 26 (range: 2–87) months. Radiation therapy was more common than radical prostatectomy (12.5% vs. 7.7%). There was 1 PCa–related death and 3 noncancer deaths. Initial adherence to AS was poor; however, men committed to AS initially were ultimately more compliant over time.

Conclusion: AS for low-risk PCa is challenging among a vulnerable population receiving care in a safety-net hospital, as rates of LTFU were high. Our findings suggest the need for AS support programs to improve adherence and follow-up among vulnerable and underserved populations. © 2017 Elsevier Inc. All rights reserved.

Keywords: Active surveillance; Prostate cancer; Safety-net hospital; Patient compliance

1. Introduction

Differential access to health care for uninsured patients remains challenging owing to financial and nonfinancial barriers [1]. Race/ethnicity, cultural differences, language barriers, and provider proximity are all important factors for uninsured or Medicaid beneficiaries to ensure appropriate follow-up [2]. After a diagnosis of cancer, routine follow-up is often required. This may present challenges for low-income individuals who have limited resources to prioritize health care [3].

For men with low-risk prostate cancer (PCa), patient compliance, follow-up, and access to care are essential components for active surveillance (AS). Current data

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support AS as a preferred strategy for most men with low-risk PCa [4,5]. In fact, men with low-risk PCa are urged to strongly consider surveillance, as the risks of immediate surgery or radiation may outweigh any benefits [6]. Under strict surveillance, men will require periodic assessment including prostate biopsies and serial serum prostate-specific antigen (PSA) testing [7]. Compliance with AS presents challenges for some patients as many protocols require quarterly screening and biennial biopsies. In 1 longitudinal AS cohort, 5% of men were lost to follow-up (LTFU) [8].

To date, it is unknown if AS is feasible in a safety-net hospital that serves primarily uninsured and Medicaid beneficiaries. Furthermore, the natural history of men on AS in a safety-net hospital is poorly understood. Our group has previously reported that men presenting to an inner-city, safety-net hospital have higher PSA levels, Gleason scores, Cancer of the Prostate Risk Assessment (CAPRA) scores [9], and ultimately higher burden of disease [10]. As such, these patient populations warrant close follow-up, especially those electing AS.

Our primary objective is to characterize men who initiated AS for PCa at a safety-net, county hospital and describe the natural history of AS in men, specifically the clinical and demographic features. We hypothesize that men on AS within a safety-net hospital represent a unique cohort of men with varying socioeconomic factors and disease-specific factors that may challenge the feasibility of AS.

2. Materials and methods

2.1. Study population

In the state of California, Medi-Cal is the state health care Medicaid benefit program for low-income individuals, serving roughly 12 million beneficiaries [11]. Of the patients enrolled in Medi-Cal, approximately 75% of the population is nonwhite and represent diverse groups including African Americans, Asians/Pacific Islanders, and Hispanics/Latinos. [11] For the uninsured of San Francisco, *Healthy San Francisco* (http://healthysanfrancisco.org/) provides an income-based sliding-scale to ensure health care benefits.

Zuckerberg San Francisco General Hospital (ZSFG) is the main public hospital for the City and County of San Francisco, California. It is designated by the Department of Public Health as a safety-net hospital and provides most of the health care services for low-income patients using Medi-Cal or uninsured patients using *Healthy San Francisco*, respectively. It is estimated that roughly 80% of ZSFG's patients use Medi-Cal or are uninsured [12]. ZSFG is vital to northern California, serving a vulnerable population including recent immigrants, elderly, disabled, disadvantaged, or homeless, or all of these.

2.2. Active surveillance at ZSFG

Currently, patients with diagnostic PSA of 10 ng/mL or less, clinical stage T1 or T2, biopsy Gleason scores 3 + 3 or 3 + 4, 33% or fewer positive cores, and 50% or less tumor in any single core are eligible for AS [13]. This has been refined further with the use of PSA density. Confirmatory 12-core prostate biopsy was recommended within 12 to 18 months of a patient's initial diagnostic biopsy to ensure adequate sampling. AS for men with low- or intermediaterisk PCa who agreed to undergo PSA screening every 3 to 6 months and a repeat biopsy every 1 to 2 years were eligible for AS at ZSFG [13–15].

2.3. Definitions of variables

A retrospective review was performed on all patients diagnosed with low-risk PCa at ZSFG who elected for AS after consultation.

Sociodemographic variables collected included age, race/ethnicity, primary language spoken, medical comorbidities, family history of PCa, and history of mental illness. Clinical data included the PSA, biopsy Gleason score, clinical stage at the time of PCa diagnosis, number of biopsy cores, number of positive cores, and CAPRA scores [9].

Variables prospectively collected and retrospectively reviewed included follow-up time, number of PSA tests, and number of follow-up biopsies. Patient outcomes included treatment received (radical prostatectomy, radiation therapy, and androgen deprivation therapy), pathologic upgrading results, and the time from diagnosis to treatment.

All prostate biopsies were performed at ZSFG, and pathology review was done internally. Patients were flagged by the electronic medical record (EMR) as LTFU after failure to contact a patient after 3 repeated phone calls, which were prompted after a missed clinic appointment. Among these patients, an in-depth chart review was performed using the EMR at ZSFG as well as EPIC Systems *CareEverywhere* that allows EMR access to non-ZSFG institutions in Northern California (e.g., UCSF, Kaiser Permanente). Following this, we defined LTFU as failure to undergo a repeat examination or a lack of serum PSA evaluation after 18 months either at ZSFG or a participating hospital in *CareEverywhere*. Our primary outcome of interest was the clinicopathologic characteristics of men on AS at ZSFG and the follow-up rates.

2.4. Statistical analysis

We used descriptive statistics to report patients' sociodemographic, clinical, and surveillance outcomes; medians and ranges for continuous variables; and number and percentage for categorical data. Kaplan-Meier curves were constructed to examine the prevalence of adherence to PSA testing every 3 to 6 months and prostate biopsies every 1 to 2 years while on AS. All statistical analyses were performed

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