

Predictive factors of unfavorable prostate cancer in patients who underwent prostatectomy but eligible for active surveillance

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Purpose: To investigate the predictive factors of unfavorable prostate cancer in Korean men who underwent radical prostatectomy but eligible for active surveillance according to Epstein criteria.

Methods: We retrospectively reviewed the medical records of 2,036 patients who underwent radical prostatectomy for prostate cancer between 1994 and 2011. Among these, 233 patients were eligible for active surveillance based on Epstein criteria. Unfavorable prostate cancer was defined as pathologic Gleason sum ≥ 7 or non-organ-confined disease. We investigated pathologic outcomes and predictive factors for unfavorable prostate cancer.

Results: Of 233 cases, 91 patients (39.1%) were pathologic Gleason sum ≥ 7 , 11 (4.7%) had extracapsular extension, and three (1.3%) had seminal vesicle invasion. Ninety-eight patients (42.1%) had unfavorable prostate cancer. When comparing clinically insignificant and significant prostate cancer, there were significant differences in mean age ($P=0.007$), prostate volume ($P=0.021$), prostate-specific antigen (PSA) density ($P=0.03$), maximum tumor volume in biopsy core ($P<0.001$), and rate of two positive cores ($P=0.001$). On multivariate analysis, age ($P=0.015$), PSA density ($P=0.017$) and two positive cores ($P=0.001$) were independent predictive factors for unfavorable prostate cancer.

Conclusions: A significant proportion of patients who were candidates for active surveillance had unfavorable prostate cancer. Age, PSA density, and two positive cores were independent significant predictive factors for unfavorable prostate cancer. These factors should be considered when performing active surveillance.

Keywords: Prostatic neoplasms, Surveillance, Prostatectomy, Pathology, Neoplasm grading

INTRODUCTION

Low-risk prostate cancer is a very indolent disease with a limited impact on life expectancy. The Scandinavian Prostate Cancer Group Study Number 4 reported that among men in the low-risk group, radical prostatectomy did not significantly reduce the rate of death from prostate cancer [1]. The Prostate Cancer Intervention versus Observation Trial compared the outcome of prostatectomy and observation and showed no

difference in cancer-specific survival among men with low-risk cancers [2]. These studies advocate the use of active surveillance (AS) and AS is now considered a viable treatment option for low-risk prostate cancer. However, these data are not directly applicable to Asian men. Center et al. [3] reported international variation in prostate cancer incidence and mortality rates. Prostate cancer incidence rates in Asia are among the lowest worldwide but the annual percent change in incidence in the Republic of Korea was 13.8%. Byun et al. [4] re-

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Submitted: 26 February 2014 / Accepted after revision: 14 April 2014

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<http://p-international.org/>
pISSN: 2287-8882 • eISSN: 2287-903X

ported that Korean men with prostate cancer now have better clinicopathologic parameters than previously. Nonetheless, they showed worse pathologic features than Western men: approximately 50% of Western men had a pathologic Gleason sum of 6 or lower compared with only approximately 30% of Korean men. Thus, although AS is a treatment option for low-risk prostate cancer in the western world it is doubtful whether this applies to Asian men. We analyzed the pathologic features of possible candidates for AS among Korean prostate cancer patients and investigated the predictive factors of unfavorable prostate cancer.

MATERIALS AND METHODS

1. Patients

We retrospectively reviewed the medical records of 2,036 patients who underwent radical prostatectomy for prostate cancer at Samsung Medical Center between September 1995 and December 2011. Patients who underwent neoadjuvant therapy and those with no biopsy slide or incomplete data were excluded. In total 233 patients fulfilled the inclusion criteria for AS defined by Carter et al. [5], which are defined as clinically localized (T1) disease, prostate-specific antigen (PSA) density ≤ 0.15 ng/mL², Gleason score ≤ 6 , fewer than three cores containing prostate cancer, and lower than 50% cancer involvement in any core [6]. We compared the pathological findings between prostate biopsies and specimens after radical prostatectomy.

Three different radical prostatectomy methods were used: 38.6% of patients (90/233) had open radical prostatectomy, 52.8% (123/233) had robot-assisted laparoscopic prostatectomy, and 8.6% (20/233) had laparoscopic radical prostatectomy. Neurovascular bundle saving was done in 78.5% (183/233). Unfavorable prostate cancer was defined as pathologic Gleason score sum ≥ 7 or non-organ-confined disease (extracapsular extension or seminal vesicle invasion) after radical prostatectomy. Our institutional pathologists reviewed all biopsy slides from other institutions. The percentage of tumor volume in each biopsy core was measured. Prostate volume was determined by transrectal ultrasound or magnetic resonance imaging using the formula $\pi/6 \times \text{width} \times \text{height} \times \text{length}$. PSA density was calculated as preoperative PSA divided by prostate volume. Biochemical recurrence (BCR) was defined as an initial serum PSA level ≥ 0.2 ng/mL with a second confirmatory serum PSA level > 0.2 ng/mL [7]. We investigated pathologic outcomes and predictive factors for unfavorable prostate cancer. Clinical and pathologic staging was assigned according to the 2002 TNM staging system.

2. Statistical analyses

Continuous variables were compared using the Mann-Whitney *U*-test, and categorical variables were compared using the chi-square test. Potential predictors for unfavorable prostate cancer were analyzed by univariable and multivariable logistic regression models. For logistic regression analysis PSA density was replaced with the transformed value of PSA density $\times 10$ (PSAD10). The 5-year BCR-free survival rate was estimated using the Kaplan-Meier method and compared using the Log-rank test. All *P*-values were two-sided, and a value of *P* < 0.05 was considered statistically significant. All data analyses were performed with IBM SPSS ver. 19.0 (IBM Co., Armonk, NY, USA).

3. Ethics statement

The study protocol was approved by the Institutional Review Board of Samsung Medical Center (IRB No. 2012-07-068). Informed consent was waived by the IRB.

RESULTS

Table 1 shows the clinical characteristics of 233 patients included in this study. Majority of enrolled patients (222/233, 95.7%) underwent radical prostatectomy after January 2005. The mean age at the time of surgery was 64.6 years (range, 43–73 years). Mean PSA level and PSA density were 4.3 ng/

Table 1. Clinical and needle biopsy characteristics of patients

Characteristic	Value
No. of patients	233
Age (yr)	64.6 \pm 6.2 (43–77)
Body mass index (kg/m ²)	24.6 \pm 2.7 (17.5–39.4)
PSA (ng/mL)	4.3 \pm 1.5 (0.91–10.80)
Prostate volume (mL)	45.1 \pm 19.4 (18.4–173.0)
PSA density (ng/mL ²)	0.10 \pm 0.03 (0.031–0.149)
Maximum tumor volume in biopsy core (%)	24.6 \pm 12.5 (1–50)
No. of biopsy cores	
<10	24 (10.3)
≥ 10	209 (89.7)
Biopsy Gleason score	
<6	6 (2.6)
6	227 (97.4)
No. of positive cores	
1	168 (72.1)
2	65 (27.9)
Laterality of biopsy cores	
Unilateral	212 (91.0)
Bilateral	21 (9.0)

Values are presented as mean \pm standard deviation (range) or number (%).

PSA, prostate specific antigen.

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