

# Combination of clinical characteristics and transrectal ultrasound-guided biopsy to predict lobes without significant cancer: application in patient selection for hemiablativ focal therapy

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**Purpose:** A major limitation of performing hemiablativ focal therapy (FT) for prostate cancer (PCa) is the possibility of accompanying significant cancer in the contralateral side of the prostate that is missed on prostate biopsy. We attempted to verify whether clinical and biopsy-related parameters can be used to predict the absence of significant cancer in the prostate lobe.

**Methods:** We assumed that hemiablativ FT could be performed in patients with low-risk PCa, with unilateral tumors as assessed by transrectal ultrasound-guided biopsy. We evaluated 214 patients who had undergone radical prostatectomy (RP) and fulfilled the eligibility criteria. Seemingly preserved lobes, defined by the absence of cancer on biopsy, were classified as lobes with no cancer (LNC), lobes with insignificant cancer (LIC), and lobes with significant cancer (LSC) according to RP pathology. Cases with an estimated tumor volume of <0.5 mL, a Gleason score of <7, and organ confinement without Gleason pattern 4 were classified as LIC. Univariate and multivariate logistic regression analyses were performed to identify predictors for LSC. Predictive accuracies of the multivariate models were assessed using receiver operating characteristic curve-derived areas under the curve.

**Results:** Of 214 evaluated lobes, 45 (21.0%), 62 (29.0%), and 107 (50.0%) were classified as LNC, LIC, and LSC, respectively. Among the clinical and biopsy-related parameters, prostate-specific antigen density and prostate volume were identified as significant predictors for LSC in univariate regression analysis. However, multivariate analysis did not identify an independent predictor. Predictive accuracies of the multivariate models did not exceed 70.4%.

**Conclusions:** Conventional parameters have limited value in predicting LSC in patients who are candidates for hemiablativ FT.

**Keywords:** Prostatic neoplasms, Tissue preservation, Patient selection

## INTRODUCTION

In the era of prostate-specific antigen (PSA) measurement, prostate cancer (PCa) is increasingly being detected at an early stage and with a low risk, but the management of local-

ized PCa remains controversial because early detection and conventional treatment do not seem to be able to reduce mortality and improve the quality of life [1,2]. Radical whole gland surgery or radiation therapy can result in substantial side effects. Urinary incontinence (5%–20%), erectile dys-

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function (30%–50%), and bowel toxicity (5%–10%) are typical complications of radical treatment [3,4]. For the treatment of low-risk PCa, active surveillance (AS) can be a treatment option; however cancer-related anxiety is the major drawback to this course [5].

Focal therapy (FT) is receiving increasing attention as a middle ground between AS and radical treatment, to selectively eradicate localized PCa while preserving uninvolved structures to minimize treatment-related side effects [6-8]. Hemiablativ FT, which involves ablation of the entire half of the prostate associated with cancer, might be the most feasible and straightforward form of FT [9]. Hemiablativ FT can be used even in cases of bilateral PCa with a significant unilateral lesion and an insignificant lesion on the contralateral side. This is because the index lesion determines the clinical outcome, and the secondary lesions are unlikely to result in disease progression [10,11]. Some authors claim that FT targeting an index lesion alone may be sufficient when supplemented with AS for the untreated insignificant lesions [7,12,13].

For the performance of appropriate hemiablativ FT, the side contralateral to the ablated lobe is supposed to contain no significant lesions. We attempted to identify conventional prostate biopsy and clinical characteristics that could predict the presence of significant cancer in the seemingly preserved lobe, contralateral to the lobe with the index lesion.

## MATERIALS AND METHODS

Between January 2008 and October 2012, 1,140 men underwent RP for PCa at Seoul National University Bundang Hospital, Seongnam, Korea. Clinical data for these men had previously been entered into a prospectively maintained computerized database. After obtaining Institutional Review Board approval, we reviewed the data on 832 of these patients who had undergone prostate biopsy using a single technique at our institution. After the measurement of prostate volume, all patients underwent transrectal ultrasound (TRUS)-guided 12-core biopsy of the prostate. The prostate was biopsied at both sides near the base, midgland, and apex, with at least six biopsy specimens obtained per side. In cases of lesions suspicious for PCa based on TRUS, one or two additional targeted biopsy specimens were obtained. Low-risk patients (clinical stage  $\leq$  T2a; Gleason score [GS]  $\leq$  6; and PSA level  $<$  10 ng/mL) with a unilateral tumor as proven by TRUS biopsy were selected as candidates for hemiablativ FT. Of the 832 patients who underwent RP using a single technique, 310 had low-risk PCa, and of these 310 patients, 214 had unilateral tumors as proven by biopsy.

All biopsy and RP specimens were analyzed by a single genitourinary pathologist (G.C.), and RP specimens were processed according to the Stanford Protocol [14]. Tumor volume was measured by multiplying the X and Y diameters and tumor depth, which was calculated according to the thicknesses of subsequent sections that showed the presence of tumor, as previously described and validated [15,16]. We classified the preserved lobes as lobes with no cancer (LNC), lobes with insignificant cancer (LIC), and lobes with significant cancer (LSC) according to the RP pathologic reports. Using the Epstein criteria [17], cases with a total tumor volume accounting for all foci of  $<$ 0.5 mL, a GS of  $<$ 7, and organ confinement without Gleason pattern 4 on one side were classified as LIC. If the index tumor was located between both lobes, we considered it to be present on the preserved side. To evaluate the possibility of preserving one lobe of the prostate by performing hemiablativ FT, LNC or LIC was considered suitable for hemiablativ FT.

## 1. Statistical analyses

Categorical variables are presented as frequencies and percentages, and continuous variables are presented as mean  $\pm$  standard deviation. Age, PSA level, percentage of positive cores among the total biopsy cores (% of positive cores), and the maximum percentage of tumor length in positive cores (% of tumor length) were entered into the models as continuous variables. Clinical T stage, PSA density (PSAD), and GS were treated as dichotomous variables. Logistic regression models were conducted for univariate and multivariate analyses to identify significant predictors of LSC. Receiver operating characteristic (ROC) curve-derived areas under the curve (AUCs) were calculated for each parameter in the multivariate model for estimating LSC. All statistical analyses were performed using IBM SPSS ver. 20.0 (IBM Co., Armonk, NY, USA). A two-tailed *P*-value of  $<$ 0.05 was considered significant for all analyses.

## RESULTS

The clinical and biopsy-related characteristics of patients are shown in Table 1. The mean patient age was  $65.14 \pm 6.82$  years. cT1b, cT1c, and cT2a disease were identified in 1 (0.5%), 174 (81.3%), and 39 patients (18.2%), respectively. The mean PSA level was  $5.56 \pm 1.20$  ng/mL, and the PSAD was  $0.16 \pm 0.08$  ng  $\cdot$  mL $^{-1} \cdot$  cm $^{-3}$ . The mean prostate volume was  $38.36 \pm 13.84$  cm $^3$ . Further, 159 (74.3%), 32 (15.0%), and 22 patients (10.3%) underwent 12-, 13-, and 14-core biopsy, respectively, and 126 patients (58.9%) showed only one positive core on TRUS-

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