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ORIGINAL ARTICLE

Configuration and validation of a novel prostate disease nomogram predicting prostate biopsy outcome: A prospective study correlating clinical indicators among Filipino adult males with elevated PSA level

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Abstract *Objective:* To configure and validate a novel prostate disease nomogram providing prostate biopsy outcome probabilities from a prospective study correlating clinical indicators and diagnostic parameters among Filipino adult male with elevated serum total prostate specific antigen (PSA) level.
Methods: All men with an elevated serum total PSA underwent initial prostate biopsy at our institution from January 2011 to August 2014 were included. Clinical indicators, diagnostic parameters, which include PSA level and PSA-derivatives, were collected as predictive factors for biopsy outcome. Multiple logistic-regression analysis involving a backward elimination selection procedure was used to select independent predictors. A nomogram was developed to calculate the probability of the biopsy outcomes. External validation of the nomogram was performed using separate data set from another center for determination of sensitivity and specificity. A receiver-operating characteristic (ROC) curve was used to assess the accuracy in predicting differential biopsy outcome.

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Results: Total of 552 patients was included. One hundred and ninety-one (34.6%) patients had benign prostatic hyperplasia, and 165 (29.9%) had chronic prostatitis. The remaining 196 (35.5%) patients had prostate adenocarcinoma. The significant independent variables used to predict biopsy outcome were age, family history of prostate cancer, prior antibiotic intake, PSA level, PSA-density, PSA-velocity, echogenic findings on ultrasound, and DRE status. The areas under the receiver-operating characteristic curve for prostate cancer using PSA alone and the nomogram were 0.688 and 0.804, respectively.
Conclusion: The nomogram configured based on routinely available clinical parameters, provides high predictive accuracy with good performance characteristics in predicting the prostate biopsy outcome such as presence of prostate cancer, high Gleason prostate cancer, benign prostatic hyperplasia, and chronic prostatitis.

1. Introduction

Recently, controversy has arisen regarding whether early detection of prostate cancer through prostate specific antigen (PSA) screening is actually beneficial or not [1]. This is so because it was known that most patients with indolent cancer may not die from it within 15 years [2]. Clinicians started to realize that the drawbacks of screening for prostate cancer with PSA alone may lead to overdetection and consequently may expose men to further intensive diagnostic screening and invasive management strategies affecting quality of life [3]. Thus, there is realization that PSA alone is not sufficient enough to justify the appropriateness of a full evaluation for prostate cancer (i.e., biopsy). There are several other clinical indicators, identified risk factors, and PSA derivatives that help increase differentiation between malignant and benign prostatic conditions, such as age, family history, race, body mass index (BMI), prior prostatitis, medications, abnormal digital rectal examination, heterogenic echo lesion on transrectal ultrasound, age-specific PSA, PSA density (PSAD), PSA velocity, and free PSA percentage [4,5].

With the advent of evidence-based medicine, bias-free prediction models such as nomogram has started to emerge in aiding clinical decision making. A nomogram is able to quantify probability of the event of interest by multivariate analysis of combined contribution of identified risk factors and clinical parameters [6]. Currently, several existing models were developed to predict positive prostate biopsy among men undergoing evaluation for prostate cancer [7]; however, these models were only able to provide prostate cancer probability, and cannot differentiate probability for clinically significant prostate cancer versus differential benign conditions. Hence, the objective of this study is to configure and validate a novel prostate disease nomogram providing prostate biopsy outcome probabilities from a prospective study correlating clinical indicators among Filipino adult male with elevated PSA.

2. Material and methods

2.1. Data source

This is a cross-sectional study prospectively collected data from all patients who had their first transrectal ultrasound (TRUS) prostate biopsy at a tertiary medical center from January 2011—August 2014. The protocol of this study was reviewed and approved by the Institutional Scientific Review Board (ISRB), Institutional Ethics Review Board (IERB), and registered at www.Clinicaltrial.gov (Identifier: NCT01826617).

Two datasets were collected uniformly for the purpose of building a clinical care prostate biopsy database in two separate institutional prostate centers. The data acquired from the main center was used to generate the nomogram, while dataset from the other center with similar biopsy protocol was used as external validation data source. Included data for analysis for the purpose of nomogram development were Filipino patients, who have PSA-based indications for prostate biopsy (elevated serum total PSA level $>$4.0 ng/mL) and gave consent for inclusion of their data into the data bank. Dataset excluded were information from non-Filipino patients, incomplete data due to patients' refusal to provide required information, patients taking Finasteride or Dutasteride, PSA obtained outside the involved institutions, past history of prior biopsy, PSA greater than 40 ng/mL, equivocal biopsy results with no confirmatory immunohistopathologic staining (includes atypical small acinar proliferation and high grade prostatic intraepithelial neoplasia) or non-adenocarcinoma that Gleason score is not applicable (i.e., lymphoma).

2.2. Clinical information

The clinical information gathered includes: (a) Identified risk factors (age, family history, race, BMI, prior prostatitis), (b) Clinical indicators of prostatic diseases (abnormal digital rectal examination, heterogenic echoic