Original Article

Development of an Indian nomogram for predicting extracapsular extension in prostate cancer

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ABSTRACT

Introduction: The aim of our study was to develop a new Indian nomogram to estimate pathologic extracapsular extension (ECE) risk in prostate cancer, by including PI-RADS v1-based magnetic resonance imaging (MRI) ECE risk score to the clinical variables used in the Partin nomogram (PN).

Materials and Methods: We analyzed 273 patients who underwent MRI of prostate and radical prostatectomy (RP). Univariate and multivariate logistic regression analyses were performed to identify predictors of ECE. We calculated the area under the receiver operating characteristic curve (AUC) for three variables used in PN and MRI ECE risk score, and a new nomogram was designed using binary logistic regression. Calibration curves assessed the agreement between the actual ECE risk and the predicted probability of the new nomogram.

Results: Out of 273 patients, 123 patients (45.1) had ECE on MRI, whereas 136 patients (49.8) had ECE on final pathology. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of MRI for predicting ECE were 76.6, 66.9, 70.0, 73.9, and 71.7 (confidence interval 95), respectively. Multivariate logistic regression analyses showed that clinical T-stage (cT), Gleason score (GS), and MRI ECE risk score remained significant. The highest and the lowest values of the AUC for single variables were 0.748 (MRI ECE risk score) and 0.636 (cT stage), respectively, and AUC for PN was 0.67. New nomogram designed using R statistical package has higher predictive accuracy (0.826) compared to PN (0.67) and good calibration.

Conclusions: MRI adds incremental value to PN. A new Indian nomogram can help in the decision-making process of nerve-sparing RP. This nomogram should be used with caution as validation is pending and will require further studies.

INTRODUCTION

Carcinoma prostate (PCa) is the second most common cancer in men in India, and a large number of patients are diagnosed at a locally advanced stage unlike in other developed countries.[1-3] Guidelines emphasize radical prostatectomy (RP) or, more recently, nerve-sparing radical prostatectomy (NSRP) as the surgery of choice for patients with localized disease, age less than 65 years, and with a mean life expectancy of at least 10 years, for better functional and oncological outcomes.[4,5] PCa with extracapsular extension (ECE) is associated with decreased overall and cancer-specific survival following RP compared to organ-confined disease.[6,7]

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Clinical staging based on physical examination has limited accuracy with 25-30% patients, with ECE being understaged preoperatively.[8] The key to prognosticate oncologic outcomes and to determine the eligibility of patients for NSRP largely depends on ECE for which predictive models have been developed. Although models such as those developed by Partin and several other authors are widely used, there is a difference between their potential and actual predictive performance in clinical practice.[9-12]

Several studies have focused on exploring the incremental value of magnetic resonance imaging (MRI) parameters

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to these predictive tools to improve the predictability of tumor staging. Prostatic MRI reporting is standardized at present with the introduction of a structured uniform reporting and scoring system (PI-RADS) and ECE risk scoring.[13] In 2015, Boesen *et al.* verified the ECE risk score in predicting ECE with relatively high accuracy.[14] However, the cumulative effect or benefit of MRI parameters among different population groups is questionable.

As there is a paucity of data in the Indian subcontinent, the aim of our study is to explore the possible incremental value of MRI to the accuracy of PN in predicting the likelihood of ECE in PCa and to develop a new nomogram from an Indian population by integrating the data of MRI ECE risk score with the clinical variables of PN.

MATERIALS AND METHODS

Patient population

This is a retrospective single-institution study of patients who underwent primary RP between 2010 and 2019. Three hundred and thirty-eight patients with biopsy-proven primary PCa were treated with RP. After excluding 65 patients who did not have complete data or had received neoadjuvant therapy, the final study population consisted of 273 patients. The collected data included prebiopsy serum prostate-specific antigen (PSA) levels, clinical T-stage (cT) determined by digital rectal examination (DRE), Gleason score (GS) from transrectal ultrasound (TRUS)-guided prostate biopsy, MRI data, and histopathologic findings from the RP specimens of all patients. Currently, the widely used PN considers clinical T stage as per AJCC guidelines. Hence, in our nomogram, clinical T stage was considered purely on DRE findings. MRI findings were added to the existing variables of PN.

Based on Harrell's guidelines, when we planned to set a nomogram for binary situations (i.e., presence or absence of ECE), the minimum value of cases needed in either group is 10 times the number of variables used for predicting. In the present study, four variables were considered therefore a minimum of 40 patients in each outcome group was needed. In this study the number of patients in the groups were, 136 with ECE and 137 without ECE, above the required number.

Magnetic resonance imaging technique

MRI information in most cases was obtained before biopsy or at least 4 weeks after biopsy to reduce the biopsy artifacts. All patients underwent multiparametric MRI (mpMRI) (202 patients) and biparametric MRI (71 patients) using a 1.5 T or 3.0 T MRI scanner without endorectal coil. The MRI characteristics of the ECE of the tumor were assessed as follows at par with the ESUR prostate MR guidelines 2012:[13] Score 0 – no sign of ECE, Score 1 – capsular abutment; Score 3 – capsular irregularity, retraction, or thickening; Score 4 – neurovascular bundle thickening and capsular signal loss or bulging; and Score 5 – direct sign of tumor tissue in the extraprostatic tissues.

MRI images of some patients done at outside centers were re-interpreted by radiologists at our institution in the absence of adequate details in the reports; certain MRI images were retrospectively analyzed for characterizing ECE risk score. In case of any discrepancy, an intradepartmental discussion was done to arrive at a unified consensus on the final report.

Pathology analysis and staging

All biopsy and surgical specimens were evaluated by two dedicated uropathologists. The location, primary and secondary GS, and the percentage of positive cores were recorded for every core of the TRUS-guided biopsy specimens. In case of any discrepancy, an intradepartmental discussion was done to arrive at the final report. In our study, 76 patients had positive surgical margins and capsular incision, mostly focal; they were included for analysis.

In the literature, two distinct definitions were considered for EPE – pT3a: the presence of tumor beyond the confines of the prostate without invasion of the seminal vesicles and whole EPE (wEPE): the presence of tumor beyond the confines of the prostate regardless of the status of seminal vesicles.[15] In our study, we have considered wEPE.

Statistical analysis

Baseline descriptive statistics were used to present demographics, tumor, and MRI data. The sensitivity, specificity, positive predictive value, and negative predictive value of MRI (index test) for the diagnosis of histological ECE (reference standard) were calculated. The 2013 Partin nomogram (PN) was used to define the predictive probability of ECE. Univariate and multivariate logistic regression analyses were performed to identify predictors of ECE. The area under the receiver operating characteristic curve (AUC) values were calculated for PSA, cT, GS, and MRI ECE risk score. A New nomogram was created by binary logistic regression analysis using 300 bootstrap resamples to decrease the overfitting bias. Univariate and multivariate logistic regression analyses were used to arrive at relative significance of variables, and the nomogram was built based on R statistical package version 3.4 (R Foundation for Statistical Computing, Vienna, Austria).

New model was constructed consisting of four variables, namely PSA, cT, GS, and MRI ECE risk score. Furthermore, calibration curves assessed the agreement between the actual ECE risk and the predicted probability of the new nomogram in the current study with an intercept (ideally to be 0) and a slope (ideally to be 1). The predictive accuracy was determined for Partin ECE score and the new model, which were quantified with AUC values and compared against each other using the DeLong's method to determine if a

significant difference was present. $P < 0.05$ was considered to be statistically significant. Statistical analysis was performed using SPSS version 22.0 (SPSS, Chicago, IL, USA) and the R statistical package version 3.4 (R Foundation for Statistical Computing, Vienna, Austria).

For collection of retrospective data, the ethics committee of Amrita Institute of Medical Sciences, Kochi institution had given approval through letter number IRB-AIMS-2020-201, 30-06-2020. All procedures adhered to the ethical guidelines of the Declaration of Helsinki and its amendments. Written permission was taken before the procedure and for the use of clinical details (without disclosing identity) for academic purpose. We confirm the availability and access of all original data reported in this study.

RESULTS

The data of 273 patients were analyzed. The demographic and preoperative data and final histopathology details are tabulated in Table 1. ECE was found on MRI in 123 patients (45.1%), whereas 136 patients (49%) had ECE on final pathology. MRI had a sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of 76.6, 66.9, 70.0, 73.9, and 71.7 (confidence interval [CI] 95), respectively, in predicting ECE. All variables except age demonstrated a statistically significant difference in detecting ECE on final pathology on univariate analyses. Based on multivariate logistic regression analyses, cT, GS, and MRI ECE risk score remained significant predictors of ECE [Table 2]. AUC values were calculated for three variables used in PN and for MRI ECE risk score to assess the accuracy of predicting ECE [Table 3].

Table 1: Summary of the patients' characteristics

Variables	Total	ECE group	Non-ECE group
Number of patients	273	136	137
Age, mean±SD (years)	64.5±6.52	64.4±6.42	64.66±6.64
PSA, mean±SD (ng/mL)	17.8±28.4	25.28±31.07	14.71±12.73
cT (DRE), *n* (%)			
cT1	66	19 (28.8)	47 (71.2)
cT2a	186	99 (53.2)	87 (46.8)
>cT2a	21	18 (85.7)	3 (14.3)
Final RP pT, *n* (%)			
pT2		136 (49.81)	
pT3a		74 (27.10)	
pT3b		58 (21.24)	
pT4		5 (1.83)	
Biopsy GS, *n* (%)			
3+3	63 (23.1)	44 (32.4)	19 (13.9)
3+4	87 (31.9)	51 (37.5)	36 (26.3)
4+3	56 (20.5)	24. (17.6)	32 (23.4)
>7	67 (24.5)	17 (12.5)	50 (36.5)
Final RP GS, *n* (%)			
3+3	30 (11)	24 (17.6)	6 (4.4)
3+4	92 (32.7)	61 (44.9)	31 (22.6)
4+3	85 (31.1)	36 (26.5)	49 (35.8)
>7	66 (24.2)	15 (11)	51 (37.2)
pLN, *n* (%)			
N0	222 (81.3)	91 (66.9)	131 (95.6)
N1	51 (18.7)	45 (33.1)	6 (4.4)

PSA=Prostate-specific antigen, cT=Clinical T stage, DRE=Digital rectal examination, RP=Radical prostatectomy, pT=Pathological T stage, GS=Gleason score, pLN=Pathological lymph node, N=Node, ECE=Extracapsular extension, SD=Standard deviation

Using R software, the new nomogram for predicting ECE was constructed based on the logistic regression analysis [Figure 1] which included cT, PSA, GS, and MRI ECE risk score. Data of 12 patients with PSA more than 60 were excluded while creating the new nomogram. The nomogram is used by first locating the patient position on each predictor variable scale, which has corresponding prognostic points (top line on vertical axis). The points for each variable were added (total points), and the corresponding probability of ECE was estimated from the bottom line. For example, if serum PSA was 15 ng/ml, biopsy Gleason sum 7 (4 + 3), clinical stage T2a, and the ECE risk score of 4, the total score would be 190, and the probability of ECE by the new model would be 85%.

For model validation, calibration was assessed. Calibration is interpreted by visual inspection of the plots of predicted probability of ECE versus actual ECE. Figure 2 presents the calibration (300 bootstrap resamples) of the nomogram. The calibration plot reflects the nomogram performance. The horizontal axis is the prediction calculated with the nomogram, and the vertical axis is the actual presence of ECE. The dashed line represents the performance of an ideal nomogram in which the predicted outcome perfectly corresponded to the actual outcome. The performance of the nomogram was tested

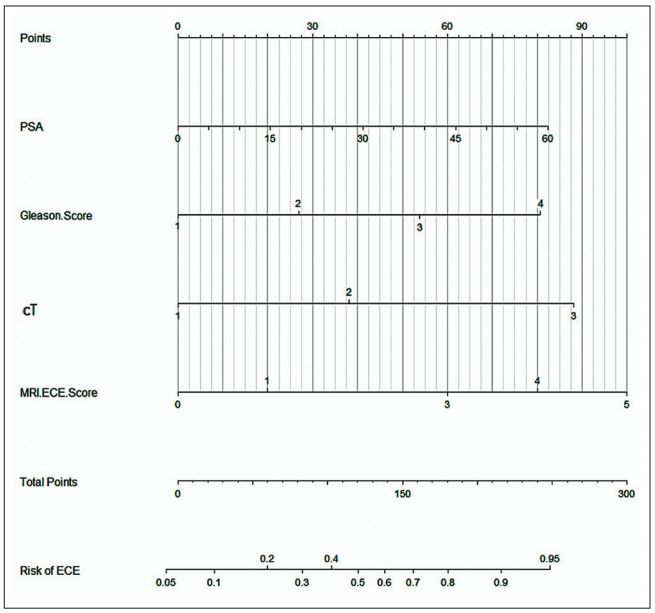

Figure 1: New nomogram predicting extracapsular extension. Prostate-specific antigen (in ng/ml); Gleason score 1 = 3 + 3, 2 = 3 + 4, 3 = 4 + 3, 4 = Gleason sum >7; cT (clinical T stage) 1 = T1c, 2 = T2a, 3 = Higher than T2a; magnetic resonance imaging extracapsular extension risk score: 0 = no sign of extracapsular extension; 1 = capsular abutment; 3 = capsular irregularity, retraction, or thickening; 4 = neurovascular bundle thickening and capsular signal loss or bulging; 5 = direct sign of tumor tissue in the extraprostatic tissues

Table 2: Factors that predict extracapsular extension based on univariate and multivariate analysis

Variables	TNM ECE		Univariate	Multivariate	
	Yes, *n* (%) 136 (49.8)	No, *n* (%) 137 (50.2)	*P*	OR (95% CI)	*P*
Age, mean±SD (years)	64.4±6.42	64.66±6.64	0.595		
MRI ECE risk score, *n* (%)					
0	45 (30.0)	105 (70.0)	<0.001	Reference	
1	2 (25.0)	6 (75.0)		7.7 (3.34-17.90)	<0.001
3	5 (31.2)	11 (68.8)		20.19 (2.92-139.3)	<0.001
4	36 (90.0)	4 (10.0)		12.15 (2.87-51.37)	0.001
5	48 (81.4)	11 (18.6)		0.360 (0.095-1.0)	0.132
Partin ECE score, mean±SD	34.86±9.33	28.07±12.51	<0.001	0.950 (0.921-0.98)	0.002
PSA, mean±SD (ng/mL)	25.28±31.07	14.71±12.73	<0.001		0.116
cT, *n* (%)					
T1c	19 (28.8)	47 (71.2)	<0.001	9.51 (1.96-45.97)	0.005
T2a	99 (53.2)	87 (46.8)		4.68 (1.03-21.27)	0.045
>T2a	18 (85.7)	3 (14.3)		Reference	
Biopsy GS, *n* (%)					
3+3	44 (69.8)	19 (30.2)	<0.001	0.095 (0.03-0.25)	<0.001
3+4	51 (58.6)	36 (41.4)		0.205 (0.084-0.49)	<0.001
4+3	24 (42.9)	32 (57.1)		0.474 (0.17-1.29)	0.145
>7	17 (25.4)	50 (74.6)		Reference	

PSA=Prostate-specific antigen, cT=Clinical T stage, GS=Gleason score, ECE=Extracapsular extension, SD=Standard deviation, MRI=Magnetic resonance imaging, TNM=Tumor, node, metastasis, OR=Odds ratio, CI=Confidence interval

Table 3: Area under the curve values for individual and combined factors in predicting extracapsular extension

Individual predictive factor	AUC (95% CI)
PSA	0.648 (0.582-0.714)
cT	0.636 (0.570-0.701)
GS	0.668 (0.605-0.732)
MRI ECE risk score	0.748 (0.688-0.808)
Combined predictive factors	
Partin nomogram (cT + PSA + GS)	0.67 (0.6403-0.7356
New Indian nomogram (cT + PSA + GS + MRI ECE risk score)	0.826 (0.7758-0.876)

PSA=Prostate-specific antigen, cT=Clinical T stage, GS=Gleason score, ECE=Extracapsular extension, AUC=Area under the curve, CI=Confidence interval, MRI=Magnetic resonance imaging

by plotting the predictions based on the nomogram without overfitting correction (apparent accuracy represented by dotted line) and bootstrap-corrected nomogram (scatter estimate of future accuracy represented by solid line). The nearness of the solid line and dashed line suggests that the nomogram-based predictions corresponded closely with actual outcomes.

In Figure 3, the 95% confidence intervals (CIs) of nomogram calibration belt did not cross the diagonal bisector line, and the *P* value in calibration test is 0.414. The predicted probability of the nomogram was consistent with the actual probability, which suggested that new nomogram had strong concordance performance, and the calibration of the prediction model is good.

The AUC values [Table 3] were 0.67 and 0.82, respectively, for the PN and the new Indian nomogram (PSA, cT, GS, and MRI ECE risk score); on DeLong's test, comparisons of AUC values between the two models were statistically significant ($P < 0.00023$).

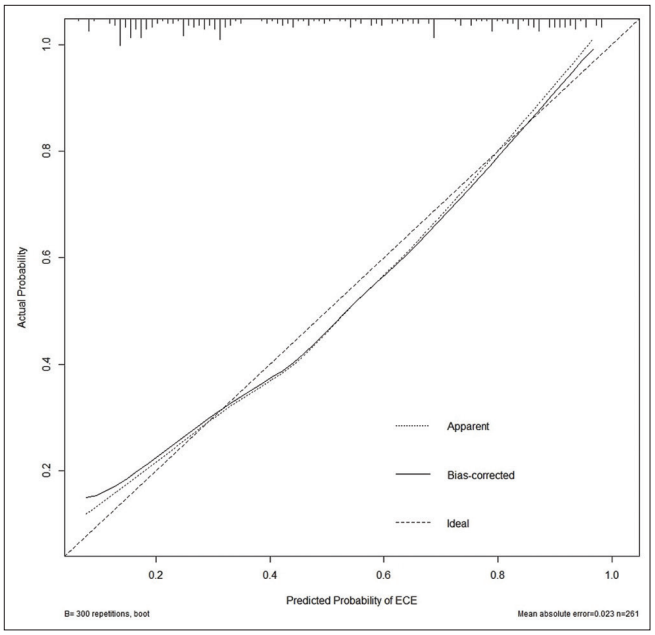

Figure 2: Calibration of the nomogram (300 bootstrap resamples). Twelve patients with prostate-specific antigen more than 60 ng/ml were excluded while constructing nomogram. Hence, *n* = 261

DISCUSSION

Distinguishing organ-confined diseases from those with ECE is often an important step in the management of PCa. ECE prediction assists in various stages of patient counseling and surgical planning, wherein if ECE is suspected, the cavernous nerves, which are responsible for erectile function, are often resected to enhance the likelihood of achieving negative margins.[16]

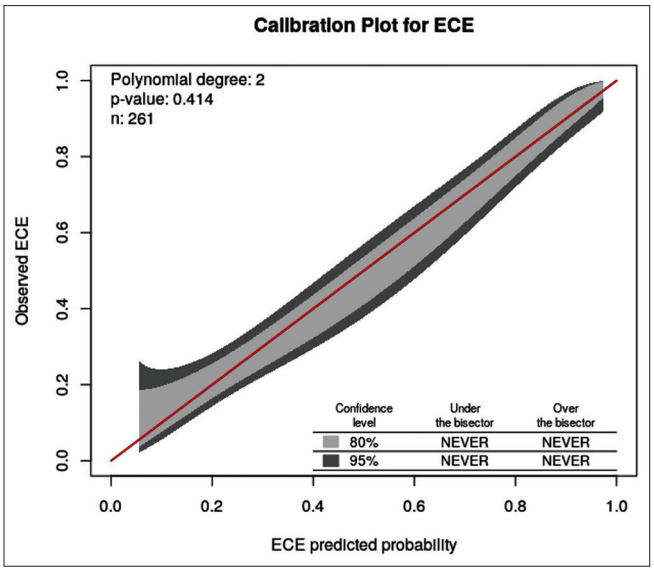

Figure 3: The 45° bisector represents the identity between predicted probabilities and observed responses. The 80% and 95% confidence level calibration belts are plotted in light and dark gray, respectively. The test's *P* value, the sample size n, and the polynomial order m of the calibration curve are reported in the top left corner. In the lower right quadrant, the times the calibration belt significantly deviates from the bisector using 80% and 95% confidence levels are reported

Despite the fact that MRI is widely adopted as a useful diagnostic and staging tool for PCa, its sensitivity in predicting ECE appears to be low to intermediate (48.7–81), and this was substantiated in this study, wherein the sensitivity was 73.4%. A few studies have compared the accuracy of MRI with standard clinical parameters such as variables of PN and have concluded that mpMRI is better for staging PCa.[17-22]

As the causative factors of prostate cancer differ epidemiologically and biologically from more developed nations,[1] the predictions based on the nomograms plotted for the population in these countries may be different for an Indian cohort.[23] The adaptability of such models to other geographic areas was poor.[15] This led us to develop a new nomogram based on the data of prostate cancer in the Indian population by adding the MRI-based ECE risk score to clinical variables.

The reported incidence of ECE in PCa has varied widely among different studies. Rocco *et al.* noted 28.4 (1803 of 6360) ECE in one American center, whereas Satake *et al.* from Japan reported 41.1 (146 of 354 patients)[15,24] and Chen *et al.* reported more than 55 of cT ≥ T3.[25] Gandaglia *et al.* study conducted across five European centers reported ECE rates of 54.[26] The ECE rate in our study was 49.8 (136 of 273 patients). In the literature, two distinct definitions were considered for ECE – (1) pT3a: the presence of tumor beyond the confines of the prostate without invasion of the seminal vesicles and (2) whole ECE (wECE): the presence of tumor beyond the confines of the prostate regardless of the status of seminal vesicles.[15] In our study, we have considered wEPE; hence, ECE rates are high, and these rates are consistent with data from other centers from India and Europe.[2,23,26]

Nomograms, in the form of user-friendly graphical interfaces, assist in clinical decision making by transforming statistical predictive models into a single numerical estimate tailored to the individual patient.[27] Several authors have developed various statistical tools to predict the pathological stage, especially after the use of PN. However, majority of those nomograms lack appropriate external validation.[15] The 2013 PN had AUC of 0.702.[10] Similarly, nomograms created using variables similar to PN by Egawa *et al.* from Japan and Song *et al.* from Korea had AUC of 0.793 and 0.626, respectively.[28,29] Memorial Sloan-Kettering cancer center (MSKCC) nomograms generated by Ohori *et al.* from the USA based on cT, PSA, Gleason sum, percentage of positive cores, and percentage of cancer involvement and Steuber *et al.* from Europe reported predictive accuracies of 0.806 and 0.840, respectively, for side-specific ECE.[11,12] The nomogram created by Satake *et al.* from Japan in 2010 with the same clinical data as MSKCC acquired an AUC value of 0.797.[24] The predictive accuracy of PN for ECE in our cohort was 0.679.

Advantages of mpMRI, widely used in these days, as an efficient imaging tool for prostate cancer staging were discussed by Sciara *et al.*[30] and were supported by Gupta *et al.*[17] who argued that mpMRI is better for staging prostate cancer than the Partin table. In 2015, Boesen *et al.* analyzed the diagnostic performance of preoperative mpMRI ECE risk score, and it showed an AUC of 0.86 with moderate inter-reader agreement ($K = 0.45$).[14] The predictive value with MRI ECE risk score was 0.748 in the current study. On applying the new nomogram which we have developed by adding the MRI ECE risk score to clinical variables of PN (PSA, cT, and GS), the predictive accuracy was found to have enhanced from 0.67 for PN to 0.82 ($P = 0.00023$). mpMRI reporting by a specialized radiologist with mpMRI prostate experience can provide good accuracy.[14,17-22,30] In view of the limited availability of radiologists trained in mpMRI, our proposed nomogram could provide incremental value to accuracy in staging ECE.

Limitations

Our study is based on results from a single-center, retrospective cohort. It is a small sample size compared to the Partin tables. There might be selection bias since the pathology and MRI revisions were not available for the entire cohort. There is a lack of uniformity in MRI timing. Besides, patients undergoing both biparametric and mpMRI were included in the study. However, since not all centers are equipped with mpMRI, and many still rely on biparametric MRI, we found this more reflective of contemporary practice in India. All GS were not based on standard sextant biopsies since some of our patients had biopsies already done elsewhere before reaching

our center, and hence, there was heterogeneity in the technique, number of cores taken, and the reporting format. Future studies are needed to validate our model with other data sets. This nomogram should be used with caution as validation was not done in other Indian populations/centers.

CONCLUSIONS

MRI adds incremental value to the existing validated risk stratification tool and provides significant additional ability for predicting ECE in prostate cancer staging. We constructed a nomogram for predicting ECE based on the results of cT, PSA, GS, and MRI ECE risk score in Indian patients. The nomogram provides a good prediction of ECE.

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