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Prostate cancer

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The Role of Digital Rectal Examination Prostate Volume Category in the Early Detection of Prostate Cancer: Its Correlation with the Magnetic Resonance Imaging Prostate Volume

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Purpose: To relate the prostate volume category (PVC) assessed with digital rectal examination (DRE)—small, median, and large—and the prostate volumes (PVs) assessed with magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS). To compare the clinically significant prostate cancer (csPCa) discrimination ability of two predictive models based on DRE-PVC and MRI-PV.

Materials and Methods: A prospective trial of 2,090 men with prostate-specific antigen >3 ng/mL and/or PCa suspicious DRE were prospectively recruited in 10 centers from Catalonia (Spain), between 2021 and 2022, in whom DRE-PVC was assessed. Pre-biopsy MRI, and 12-core TRUS-random biopsy was always performed after 2- to 6-core TRUS-fusion targeted biopsy of prostate imaging-report and data system >3 lesions. In 370 men (17.7%) the DRE-PVC was unconclusive. Among the 1,720 men finally analyzed the csPCa (grade group >2) detection was 42.4%.

Results: The median (interquartile range) of TRUS and MRI-PVs of small prostates were 33 mL (19–37 mL) and 35 mL (23–30 mL), p=0.410; in median prostates they were 51 mL (38–58 mL) and 55 mL (48–63 mL) respectively, p<0.001; in large prostates 80 mL (60–100 mL) and 95 mL (75–118 mL) respectively, p<0.001. The predictive models sharing the MRI-PV and DRE-PVC showed areas under the curves of 0.832 (95% confidence interval [CI], 0.813–0.851) and 0.828 (95% CI, 0.809–0.848) respectively, p=0.632, as well as similar net benefit and clinical utility.

Conclusions: PVC was unconclusive in 17% of DREs. MRI-PV overestimated the TRUS-PV in median and large prostates. The predictive models based on MRI-PV and DRE-PVC showed similar efficacy to predict csPCa. PVC assessed with DRE is helpful to predict the csPCa risk before MRI.

Keywords: Digital rectal examination; Magnetic resonance imaging; Predictive model; Prostate volume; Prostate volume category; Transrectal ultrasound

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INTRODUCTION

The European Union currently proposes to support member states incorporating prostate cancer (PCa) screening based on serum prostate-specific antigen (PSA) and magnetic resonance imaging (MRI) [1]. This is based on the evidence that early detection of clinically significant PCa (csPCa) reduces the specific mortality of PCa [2]. After the introduction of multiparametric MRI (mpMRI) and MRI-targeted biopsies, the focus of PCa screening has changed from the overall PCa towards csPCa, also decreasing unnecessary prostate biopsies and the overdetection of insignificant tumors [3]. Currently, the prostate biopsy is recommended according to the prostate imaging-report and data system (PI-RADS). Prostate biopsy is usually avoided in men with negative mpMRI (PI-RADS <3) because its negative predictive value can reach up to 95% [4]. The consequence of the current strategy for the early detection of csPCa has been a significant increase in the demand of prostate mpMRI exams that is not acceptable for some health systems [5]. In addition, because uncertain scenarios after mpMRI remain, having high rates of unnecessary biopsies and overdetection of insignificant tumors [6], the European Association of Urology recommends risk-organized models to avoid unnecessary mpMRI exams and prostate biopsies by sequencing appropriate tools [7]. Risk calculators can individualize the likelihood of csPCa, improving the selection of candidates for mpMRI and prostate biopsy, been the prostate volume (PV) a weighed independent predictor of csPCa always incorporated in these tools [8]. Currently, the PV is accurately assessed with MRI, whereas transrectal ultrasound (TRUS) has been the standard method for assessing the PV just before prostate biopsy until the spread of MRI [9]. Because TRUS is not usually performed prior to the prostate biopsy with the sole aim of measuring the PV, Roobol et al [10] proposed, in 2012, the assessment of the prostate volume category (PVC) from DRE and then estimating the PV from the median value observed in each category (small, median, and large), to be used in the Rotterdam risk calculator. We recently have developed the Barcelona risk calculator-1 to predict the risk of csPCa before mpMRI, incorporating the DRE-PVC as a predictive variable beyond the age, type of biopsy (initial *vs.* repeated), PCa family history, serum PSA and DRE (normal *vs.* anormal), with the aim of reducing the demand of mpMRI exams [11].

Because the relationship between DRE-PVC and MRI-PV has never been reported, we aim to analyze this relationship and that with TRUS-PV, in a large series of men with suspected PCa in whom DRE-PVC was assessed. We also aim to compare the csPCa discrimination ability of csPCa of two predictive models developed from the DRE-PVC and the MRI-PV.

MATERIALS AND METHODS

This prospective trial included 2,090 men with suspected PCa, PSA >3.0 ng/mL and/or DRE suspicious of PCa, recruited from 10 centers from Catalonia (Spain) between 2021 and 2022, in whom DRE-PVC was assessed. Pre-biopsy mpMRI was always performed as well as 12-core TRUS systematic biopsy and 2 to 6-core TRUS-MRI fusion target biopsy of PI-RADS >3 lesions. A subset of 370 men (17.7%) was excluded due to an unconclusive DRE-PVC. The PVC was assessed through DRE by one senior urologist in each center during the pre-biopsy medical evaluation or just before the prostate biopsy. The PVC was classified as "small, median, and large". The main reason for unconclusive DRE-PVC was the impossibility to explore the entire posterior gland surface mainly due to its high location. The PV reported with the MRI and TRUS exams was calculated from the ellipsoid formula [12]. The DRE-PVC and the MRI-PV were included in two predictive models to assess the individual likelihood of csPCa beyond the age (years), serum PSA (ng/mL), DRE (normal *vs.* abnormal), PCa family history (first degree *vs.* no), type of biopsy (repeated *vs.* initial), and PI-RADS score [13]. The csPCa was defined when the International Society of Urologic Pathology grade group was 2 or higher [14].

The research protocol was approved by the Institutional Clinical Research Ethics Committee (PR-AG-317/2017) in accordance with the Declaration of Helsinki. Informed consent was signed by all participants. Data from participant centers were submitted anonymized.

Quantitative variables were expressed in median and interquartile range (IQR, 25 to 75 percentile). Qualitative variables were expressed in percentages. The associations between quantitative variables were analyzed with the Mann–Whitney U test when independent variables and the Wilcoxon test when paired variables

[15], and those between qualitative variables with the chi-square test [16]. Binary logistic regression analysis was performed to develop the predictive models and generate individual likelihoods of csPCa [17]. The discrimination ability for csPCa was analyzed with receiver operating characteristic (ROC) curves and the areas under the curve (AUC) were compared with the Delong test [18,19]. Decision curve analysis (DCAs) were developed to assess the net benefit [20], and clinical utility curve (CUC) to access the differential between saved biopsies and undetected csPCa in a continuous csPCa probability threshold [21]. The efficacy of 0.95 and 0.90 sensitivity cut-offs was evaluated comparing their corresponding specificities. Values of $p<0.05$ were considered significant. Statistical analyses were computed using R programming language v.4.0.3 (The R Foundation for Statistical Computing) and SPSS v.25 (IBM Corp.).

Table 1. Characteristics of included men

Characteristic	Measurement
Number of men	1,720
Median age (y)	68 (62–74)
Median serum PSA (ng/mL)	7.4 (5.4–11.9)
Abnormal DRE	484 (28.1)
PCa family history	109 (6.3)
Repeat biopsy	535 (31.1)
Median PV (mL)	55 (40–80)
PI-RADS score	
1	167 (9.7)
2	15 (0.9)
3	416 (24.2)
4	713 (41.5)
5	409 (23.8)
PCa detection	1,049 (61.0)
csPCa detection	729 (42.4)

Values are presented as median (interquartile range) or number (%).
PSA: prostate-specific antigen, DRE: digital rectal examination, PCa: prostate cancer, PV: prostate volume, PI-RADS: prostate imaging-report and data system, csPCa: clinically significant PCa.

RESULTS

Among the 1,720 participants finally included the median age was 68 years, the median serum PSA was 7.4 ng/mL, and abnormal DRE was found in 28.1%. The rate of negative mpMRI (PI-RADS <3) was 10.6%, been in 24.2% of PI-RADS 3, 41.5% of PI-RADS 4, and 23.8% of PI-RADS 5. The median MRI-PV was 55 mL

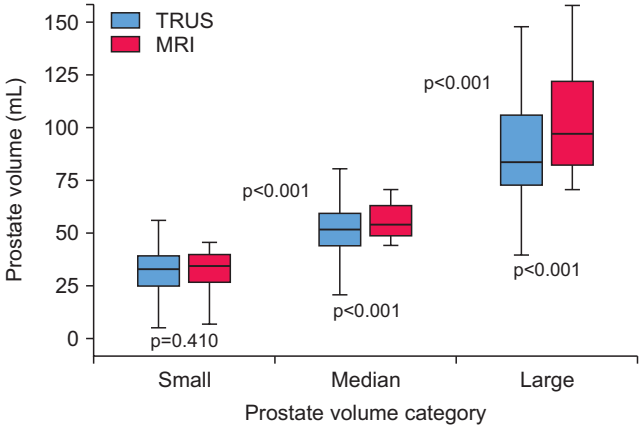

Fig. 1. Boxplots showing the TRUS and MRI-prostate volumes corresponding to each DRE-prostate volume category. TRUS: transrectal ultrasound, MRI: magnetic resonance imaging, DRE: digital rectal examination.

Table 2. Logistic regression of predictive variable of csPCa in the model including the PV assessed with MRI and the model including the PVC assessed with DRE

Predictive variable	Model with MRI-PV		Model with DRE-PVC	
	Odds ratio (95% CI)	p-value	Odds ratio (95% CI)	p-value
Age (ref. previous year)	1.06 (1.04–1.08)	<0.001	1.05 (1.04–1.07)	<0.001
Serum PSA (ref. previous ng/mL)	1.03 (1.02–1.07)	0.032	1.01 (1.00–1.01)	0.027
DRE (ref. normal)	1.62 (1.24–2.11)	<0.001	1.68 (1.29–2.18)	<0.001
MRI-PV (ref. previous mL)	0.98 (0.81–0.98)	<0.001	-	-
DRE-PVC (ref. small)	-	-	0.56 (0.47–0.66)	<0.001
Type of biopsy (ref. initial)	0.71 (0.55–0.92)	0.009	1.63 (0.49–0.81)	<0.001
PCa family history (ref, no.)	1.07 (1.01–1.18)	0.029	1.79 (1.05–1.12)	0.036
PI-RADS score (ref. 1)	3.16 (2.69–3.71)	<0.001	3.24 (2.77–3.79)	<0.001

csPCa: clinically significant PCa, MRI: magnetic resonance imaging, PV: prostate volume, DRE: digital rectal examination, CI: confidence interval, Ref: reference, PSA: prostate-specific antigen, PVC: prostate volume category, PCa: prostate cancer, PI-RADS: prostate imaging-report and data system.

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(IQR, 39–75) whereas that of TRUS-PV 50 mL (27–67) p<0.001. The PCa detection was 61.0% and that of csPCa 42.4% (Table 1).

DRE-PVC corresponded to small prostates in 319 men (18.5%), median prostates in 896 (52.1%), and large prostates in 505 (29.4%). The boxplots of TRUS-PV and MRI-PV according to the DRE-PVCs (Fig. 1) showed in small prostates a median TRUS-PV of 33 mL (IQR, 19–37) whereas 35 mL (23–40) of MRI-PV p=0.410; in median prostates these volumes were 51 mL (38–58) and 55 mL (48–63) respectively, p<0.001; in large prostates they were 80 mL (80–100) and 95 mL (75–118) respectively, p<0.001.

The logistic regression analysis of predictors in developed models reflected a different weigh of MRI-PV and DRE-PVC, been both independent predictive variables of csPCa (Table 2). Individual probabilities of csPCa were generated from both models, and csPCa discrimination analysis of the models including the MRI-PV and the DRE-PVC (Fig. 2), exhibited AUCs of 0.832 (95% confidence interval [CI], 0.813–0.851) and 0.828 (95% CI, 0.809–0.848), respectively, p=0.632. The specificities reported with the 0.95 and 0.90 csPCa sensitivity cut-offs were 0.38 and 0.55 compared to 0.36 and 0.55, respectively, p=0.876 and p=1.000 (Table 3). DCAs showed same benefit of both models (Fig. 3), and CUCs showed similar clinical utility of both models in terms of saved biopsies and undetected csPCa (Fig. 4).

To know the benefit of sharing DRE-PVC in the model developed to save mpMRI exams, we present the ROC curves of the models to predict csPCa, sharing or not DRE-PVC (Fig. 5). The model sharing, age, PSA, DRE (normal *vs.* suspicious), type of prostate biopsy (initial *vs.* repeated) and DRE-PVC presented an AUC of 0.723 (95% CI, 0.699–0.747) and the model without DRE-PVC 0.695 (95% CI, 0.670–0.721), p=0.007. The nomogram of the model including DRE-PVC was also developed (Fig. 6).

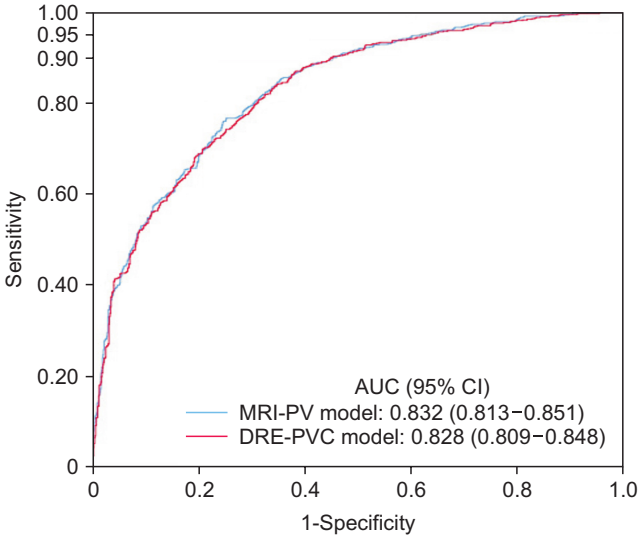

Fig. 2. Clinically significant prostate cancer discrimination ability of the models sharing the MRI-prostate volume (PV) and the DRE-prostate volume category (PVC). MRI: magnetic resonance imaging, DRE: digital rectal examination, AUC: areas under the curve, CI: confidence interval.

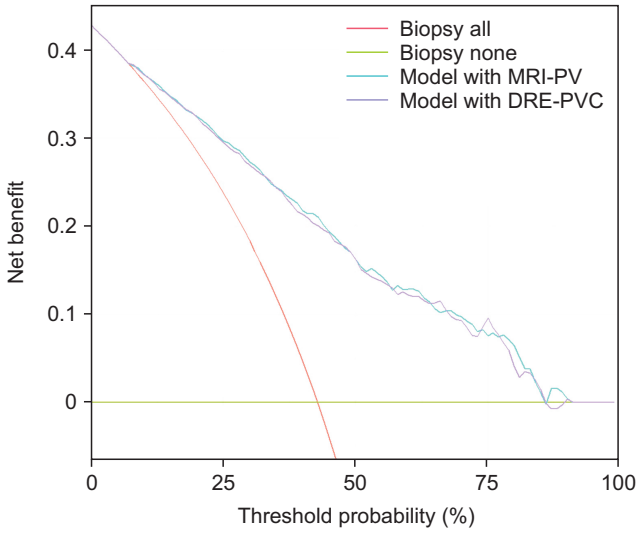

Fig. 3. Decision curve analysis showing the similar net benefit obtained with the models sharing MRI-prostate volume (PV) and DRE-prostate volume category (PVC) over biopsying all men. MRI: magnetic resonance imaging, DRE: digital rectal examination.

Table 3. Cut-offs with 0.95 and 0.90 sensitivity and their corresponding specificities of predictive models sharing MRI-PV and DRE-PVC

Predictive model	Cut-off	Sensitivity				p-value
		0.95	p-value	Cut-off	0.90	
With MRI-PV	0.16	0.38	0.876	0.27	0.55	>0.999
With DRE-PVC	0.16	0.36		0.27	0.55	

MRI: magnetic resonance imaging, PV: prostate volume, DRE: digital rectal examination, PVC: prostate volume category.

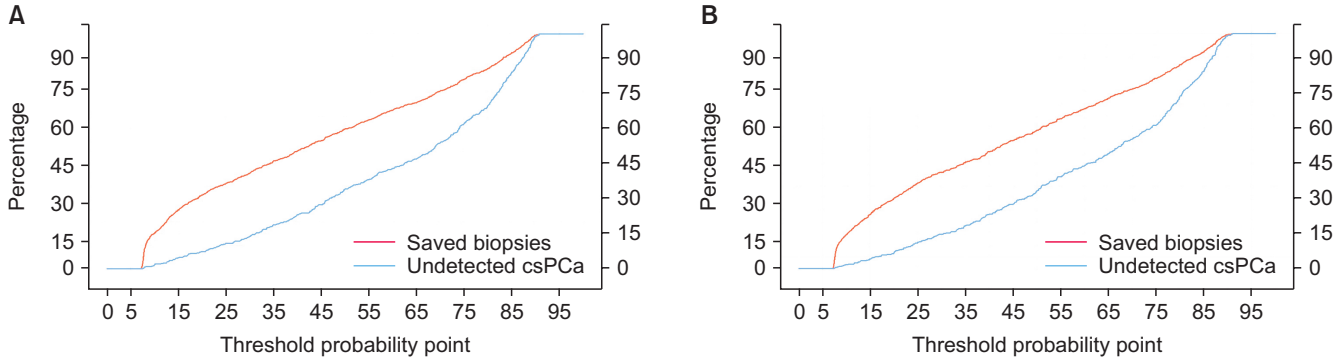

Fig. 4. Clinical utility curve showing the similar utility of the models sharing the MRI-prostate volume (A) and DRE-prostate volume category (B), in terms of saved prostate biopsies and undetected csPCa. MRI: magnetic resonance imaging, DRE: digital rectal examination, csPCa: clinically significant prostate cancer.

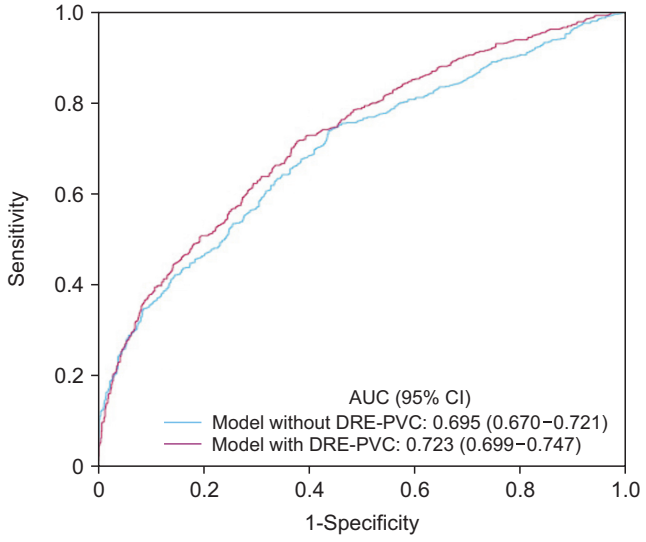

Fig. 5. Clinically significant prostate cancer discrimination ability improvement of the model developed to save multiparametric MRI exams when DRE prostate volume category (PVC) is shared. MRI: magnetic resonance imaging, DRE: digital rectal examination, AUC: areas under the curve, CI: confidence interval.

DISCUSSION

The present study reports the relationship between the PV assessed with MRI and the PVC assessed with DRE. In 2012, Roobol et al [10] reported the relationship between DRE-PVCs and TRUS-PV in a similar study carried out on 322 men with suspected PCa. We report that TRUS underestimates the PV compared with MRI, especially in median and large prostate glands, as other studies have suggested previously [12,22]. The median PV measured with TRUS in small prostates was 33 mL compared to that of 27 mL reported by Roobol et al [10]. However, in median prostates these volumes were 51 mL *vs.* 46 mL, and 80 mL and 70 mL in large prostates respectively, been significative these differences while not that observed in small prostates. These differences may be related with the lower PV of the screening population of the Rotterdam section of ERSPC trial than that observed in our study that included men older men. It has been reported that PV assessed with DRE has a low correlation with the true PV assessed in surgical specimens of radical prostatectomy, compared with the measurements from TRUS and MRI [23-25]. However, other studies suggest that DRE-PV is useful in prostates glands from 30 mL, especially to establish certain cut-offs with clinical interest [26-28]. What has not been reported, but is known by all urologists, is the impossibility of palpating the entire prostate gland surface due to its high location which occurred in 17% of the participants in our study.

Although the DRE-PVC estimates the PV with little precision than TRUS [10], we observed that it was an independent predictive variable of csPCa in the logistic regression analysis as the MRI-PV was. This fact is important because it is the foundation to share DRE-PVC in the predictive models developed to avoid unnecessary MRI exams. Currently, PV is not available before MRI and DRE is to the only way assess this independent predictor of csPCa [8,11,28]. In addition, we have shown how the predictive model for csPCa, when mpMRI is not available benefits from sharing DRE-PVC. Therefore, we vindicate the importance of DRE during the early detection of csPCa, not only to palpate abnormalities suggesting PCa in the posterior prostate gland surface but also to assess the PVC as an important predictor of csPCa [11,29].

What seems interesting is to know that pathophysiologic reasons for the association of PV and csPCa in-

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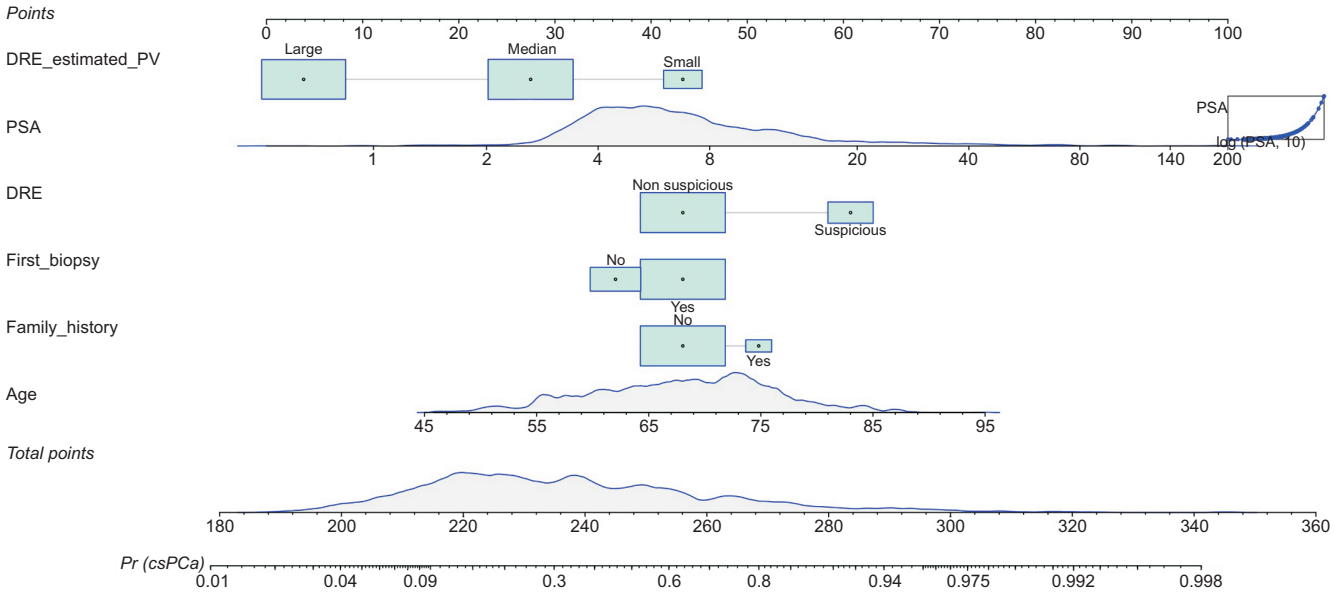

Fig. 6. Nomogram of the csPCa predictive model developed to save multiparametric MRI exams which shares DRE prostate volume category (PVC). csPCa: clinically significant prostate cancer, MRI: magnetic resonance imaging, DRE: digital rectal examination, PSA: prostate-specific antigen.

cidence are related with the histo-anatomical changes within the peripheral zone of prostate gland induced by the pressure of the hyperplasic transition zone, leading to significant epithelial cell atrophy and fibrosis due to direct pressure-related tissue injury and reduced blood flow tissue transformation. As 80% of PCa originates from the glandular epithelium within the peripheral zone this supports the hypothesis that these dynamic interactions between the growing transition zone and compressed peripheral zone explain the decreased incidence of PCa in large BPH prostates as inversely in small prostates [29-31].

The present study has the strengths of its prospective and multicenter design and the large size of the analyzed series. A limitation was the definition of csPCa in prostate biopsies which has low relationship with the true pathology assessed in radical prostatectomy surgical specimens. Although DRE-PVC was assessed by staff urologists, inter-observational variability has been described [32,33]. The inability to compare models that completely exclude information from MRI to MRI-based models is a limitation that we overcame by creating another model that minimizes inferiority compared to a model that includes the information available from the MRI.

CONCLUSIONS

The assessment of PVC from DRE is an important predictor of csPCa when the PV from TRUS or MRI is not available, which can be shared in predictive models to decrease MRI demand.

Conflict of Interest

The authors have nothing to disclose.

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None.

Author Contribution

Conceptualization: JM. Data curation: JMA, PS, NP, JMR, NP, XRP, MVMR, GGM, AC. Formal analysis: JM, BM. Funding acquisition: JM, Investigation: JM, JMA, PS, BM. Methodology: JM, BM. Project administration: JM. Resources: JM. Supervision: JM. Validation: JM. Visualization: JM. Writing – original draft: JM. Writing – review & editing: JM, JMA, PS.

Data Sharing Statement

The data analyzed for this study have been deposited in HARVARD Dataverse and are available at https://doi.org/10.7910/DVN/DAZPCX.

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