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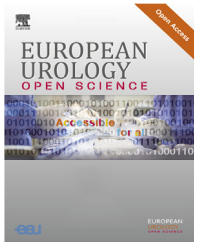

European Association of Urology

Brief Correspondence

Evaluating the Quality of Local Programs for Early Detection of Significant Prostate Cancer

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Abstract

Quality control of programs for detection of significant prostate cancer (sPCa) could be defined by the correlation between observed and reference 95% confidence intervals (CIs) for Prostate Imaging-Reporting and Data System (PI-RADS) categories. We used the area under the receiver operating characteristic curve (AUC) for the Barcelona magnetic resonance imaging (MRI) predictive model to screen the quality of ten participant centers in the sPCa opportunistic early detection program in Catalonia. We set an AUC of <0.8 as the criterion for suboptimal quality. Quality was confirmed in terms of the correlation between actual sPCa detection rates and reference 95% CIs. For a cohort of 2624 men with prostate-specific antigen >3.0 ng/ml and/or a suspicious digital rectal examination who underwent multiparametric MRI and two- to four-core targeted biopsies of PI-RADS ≥3 lesions and/or 12-core systematic biopsy, AUC values ranged from 0.527 to 0.914 and were <0.8 in four centers (40%). There was concordance between actual sPCa detection rates and reference 95% CIs for one or two PI-RADS categories when the AUC was <0.8, and for three or four PI-RADS categories when the AUC was ≥0.8. A review of procedures used for sPCa detection should be recommended in centers with suboptimal quality.

Patient summary: We tested a method for assessing quality control for centers carrying out screening for early detection of prostate cancer. We found that the method can identify centers that may need to review their procedures for detection of significant prostate cancer.

The European Union currently suggests risk-stratified screening for prostate cancer (PCa) on the basis of serum prostate-specific antigen (PSA) measurement and magnetic resonance imaging (MRI) [1]. This new paradigm for PCa screening is focused on early detection of significant PCa (sPCa). The European Association of Urology recommends using stratification pathways that are based on predictive models to improve the efficiency of current sPCa early

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detection by decreasing the demand for MRI examinations, unnecessary prostate biopsies, and overdetection of insignificant PCa [2].

The Barcelona MRI predictive model (BCN-MRI-PM) has been externally validated in the opportunistic sPCa screening program in Catalonia, a Spanish region with 7.9 million inhabitants. After this validation we observed suboptimal discrimination ability for sPCa in terms of area under the curve receiver operating characteristic curve (AUC) values of <0.8 for the BCN-MRI-PM for four of ten participating centers [3,4]. This situation called into question the quality of the diagnostic approach used in these centers. However, no method for assessing quality control for centers participating in sPCa screening programs exists. Quality criteria for MRI acquisition (PI-QUAL), interpretation, and radiologists' training have been established [5–7], but there are no clear recommendations on how to perform segmentation of suspicious lesions, MRI-ultrasound fusion images, and targeted biopsies beyond use of the transperineal route and adding 12-core systematic biopsies or performing perilesional biopsies. The optimal scheme for prostate biopsies and the appropriate number of cores obtained during targeted biopsy remain uncertain [8,9].

In 2005, Kelleger and Armstrong proposed AUC estimation for predictive models as an approach to assess the quality of diagnostic procedures [4]. We hypothesized that local quality control of the opportunistic sPCa screening program in Catalonia could be assessed using the AUC for the BCN-MRI-PM. Our objective was to screen the local quality of participating centers and confirm this quality via correlation between the sPCa detection rates observed and the reference 95% confidence intervals (CIs) reported for the Prostate Imaging-Reporting and Data System (PI-RADS) v2.1 categories [10].

The aims in the prospective trial conducted for BCN-MRI-PM validation in the opportunistic sPCa screening program in Catalonia were: (1) to establish the PCa suspicion for men with serum PSA >3.0 ng/ml and/or an abnormal digital rectal examination (DRE); (2) to perform prebiopsy multiparametric MRI and report results using PI-RADS v2.1; (3) to perform two- to four-core targeted biopsies of PI-RADS $\geq$3 lesions and/or 12-core systematic biopsies; and (4) to consider sPCa for lesions with International Society of Urologic Pathology grade group $\geq$2. The trial was approved by the ethics committee of Vall d'Hebron University Hospital (PRAG-02/2021).

Among 2624 men consecutively included between 2021 and 2022, PCa was suspected on the basis of serum PSA >3.0 ng/ml in 2511 (95.7%) and an abnormal DRE alone in 113 (4.3%). Targeted biopsies of PI-RADS $\geq$3 lesions and 12-core systematic biopsies were conducted for 2414 men (92.0%), while 12-core systematic biopsies alone were performed for 210 men (8.0%) with PI-RADS <3 lesions because of high risk of sPCa. The diagnostic pathway in each participating center involved experienced radiologists, urologists, and pathologists. The overall characteristics of this validation cohort are summarized in Supplementary Table 1. The characteristics by participating center are compared in Supplementary Table 2. We noted significant differences for all the characteristics analyzed, highlighting the variability among local cohorts despite use of the same criteria for PCa suspicion. Logistic regression analysis revealed many independent variables predictive of sPCa apart from the PI-RADS score (Supplementary Table 3). The sPCa detection rate was 44.8% overall and ranged from 34.5% to 64.8% among the centers.

The distribution of sPCa detection rates by PI-RADS v2.1 category (1–2, 3, 4, and 5) in each participating center is summarized in Supplementary Table 4. The sPCa detection rate ranged from 0% to 100% for PI-RADS <3, from 0% to 41.3% for PI-RADS 3, from 4.6% to 64.3% for PI-RADS 4, and from 40% to 100% for PI-RADS 5. The AUC for the BCN-MRI-PM was 0.828 (95% CI 0.808–0.840) overall and ranged from 0.527 (95% CI 0.393–0.661) to 0.914 (95% CI 0.873–0.955) across the participating centers. AUC <0.7 was observed in one center (10%), AUC between 0.7 and 0.79 in three centers (30%), AUC between 0.8 and 0.86 in three centers (30%), and AUC >0.86 in three centers (30%; Supplementary Table 5). Figure 1A–D shows examples for each AUC category. The degree of concordance between the sPCa detection rate observed and the reference 95% CI for each PI-RADS v2.1 category [10] is presented in Figure 1E. There was concordance for one or two of the four PI-RADS categories analyzed when the AUC was suboptimal (<0.8) and for three or four categories when the AUC was optimal ($\geq$0.8) existed. Supplementary Table 6 summarizes the reference rates for sPCa detection by PI-RADS category and the corresponding 95% CIs [10].

The BCN-MRI-PM was successfully validated in the opportunistic sPCa screening program in Catalonia despite the suboptimal quality observed in 40% of participating centers. This suboptimal quality was screened using the BCN-MRI-PM and confirmed by lack of concordance between sPCa detection rates and reference 95% CIs by PI-RADS v2.1 category. Besides differences in baseline characteristics for men screened in the participating centers, this finding may suggest low quality of MRI reporting, suboptimal segmentation of suspected lesions, or inappropriate prostate biopsy procedures. The lack of concordance between the sPCa detection rates observed in the centers and the reference 95% CIs for each PI-RADS category confirms suboptimal quality [10]. In our opinion, suboptimal quality for centers participating in a PCa screening program could affect the ultimate aim of PCa screening, which is to decrease PCa mortality.

Our study is limited by its retrospective design. The reference 95% CIs for sPCa detection rates by PI-RADS v2.1 category were obtained from a meta-analysis that lacked standardized diagnostic procedures [10]. PI-RADS scores 1 and 2 were considered as a single category owing to the small number of cases considered for prostate biopsy. Our proposed method for assessing the quality of sPCa screening

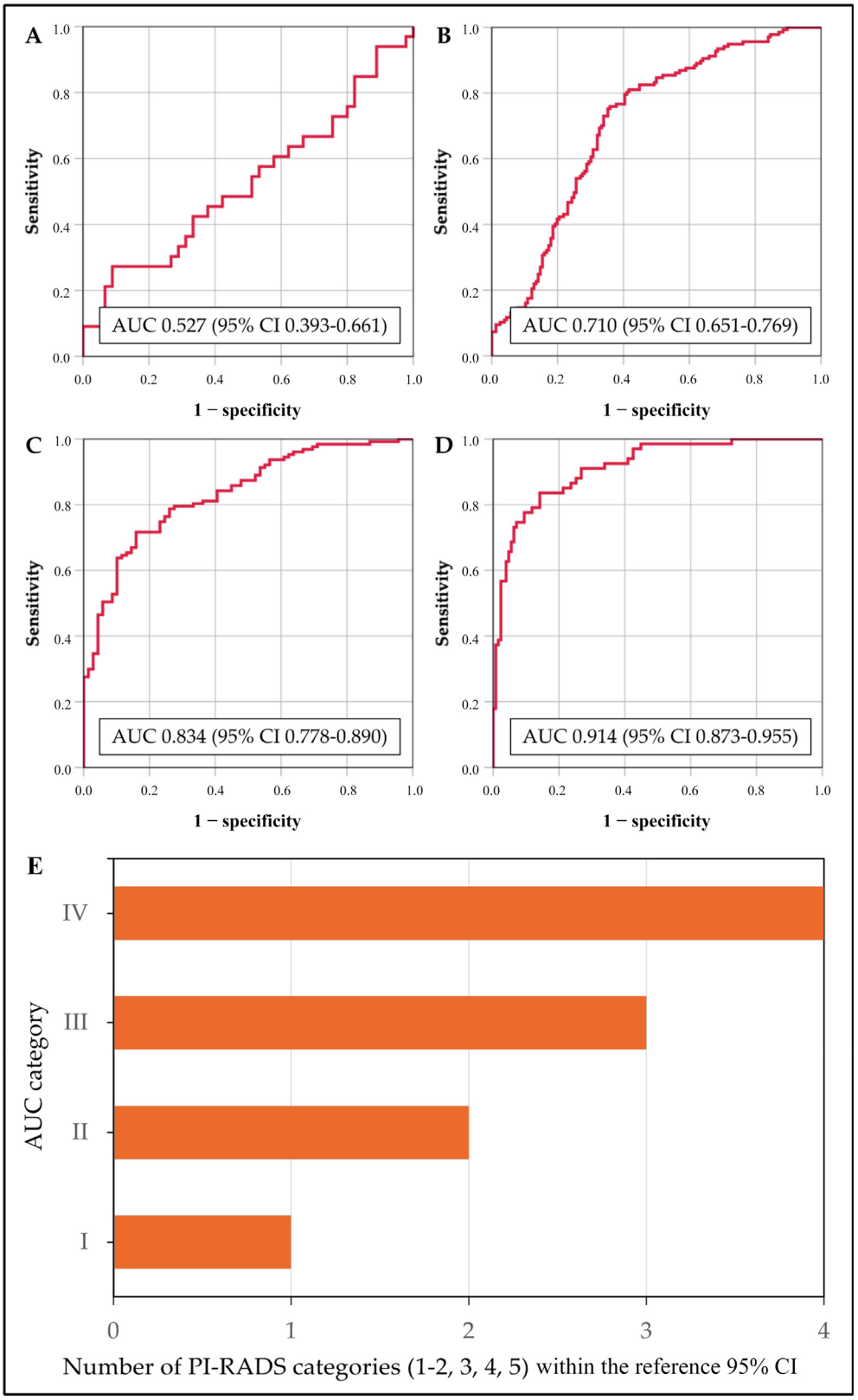

Fig. 1 – (A–D) Receiver operating characteristic curve analysis showing four AUC categories for the Barcelona magnetic resonance imaging predictive model among centers participating in the opportunistic screening program for significant prostate cancer in Catalonia. (A) Category I, AUC <0.7; (B) category II, AUC between 0.7 and 0.79; (C) category III, AUC between 0.8 and 0.85; and (D) category IV, AUC ≥0.86. (E) Degree of concordance between the detection rate observed for significant prostate cancer and the reference 95% CI reported for each PI-RADS v2.1 category [10]. AUC = area under the receiver operating characteristic curve; CI = confidence interval; PI-RADS = Prostate Imaging-Reporting and Data System.

programs cannot distinguish between deficits in MRI reporting, lesion segmentation, and prostate biopsy procedures.

We investigated how the quality of centers participating in an opportunistic sPCa screening program can be assessed. Suboptimal quality was detected for 40% of the centers, providing an opportunity to review diagnostic procedures, especially MRI reporting, lesion segmentation, and prostate biopsy. Our findings need to be confirmed in further studies.

Author contributions: Juan Morote had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Morote, Paesano.
Acquisition of data: Paesano, Picola, Muñoz-Rodriguez, Ruiz-Plazas, Muñoz-Rivero, Celma, García-de Manuel, Abascal, Servian.
Analysis and interpretation of data: Morote.
Drafting of the manuscript: Morote.
Critical revision of the manuscript for important intellectual content: Paesano, Abascal, Servian.
Statistical analysis: Morote.
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Data sharing statement: The data presented in this study are available on request from the corresponding author.

Ethics considerations: This study was approved by the ethics committee of the coordinating center (PRAG20/002). Written informed consent was obtained from all participants.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2024.06.002.

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