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# Artificial intelligence and radiologists in prostate cancer detection on MRI (PI-CAI): an international, paired, non-inferiority, confirmatory study

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# Artificial intelligence and radiologists in prostate cancer detection on MRI (PI-CAI): an international, paired, non-inferiority, confirmatory study

*Anindo Saha*, Joeran S Bosma*, Jasper J Twilt*, Bram van Ginneken, Anders Bjartell, Anwar R Padhani, David Bonekamp, Geert Villeirs, Georg Salomon, Gianluca Giannarini, Jayashree Kalpathy-Cramer, Jelle Barentsz, Klaus H Maier-Hein, Mirabela Rusu, Olivier Rouvière, Roderick van den Bergh, Valeria Panebianco, Veeru Kasivisvanathan, Nancy A Obuchowski, Derya Yakar, Mattijs Elschot, Jeroen Veltman, Jurgen J Fütterer, Maarten de Rooij†, Henkjan Huisman†, on behalf of the PI-CAI consortium‡*

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# Background

- Artificial intelligence (AI) systems can potentially aid the diagnostic pathway of prostate cancer by
  - alleviating the increasing workload
  - preventing overdiagnosis
  - reducing the dependence on experienced radiologists
- Authors aimed to investigate the performance of AI system at detecting Prostate cancer on MRI when compared to radiologists using the PI-RADS (V 2.1) scoring

# Methodology

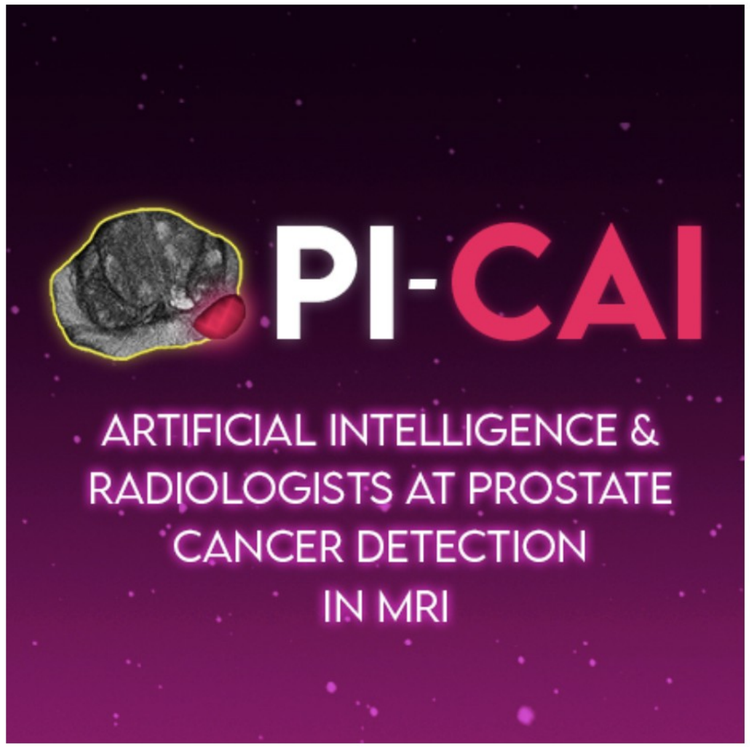
- International, paired, non-inferiority, confirmatory study

https://grand-challenge.org/algorithms/pi-cai-pubpriv-datascientx/

## Interfaces

This algorithm implements all of the following input-output combinations:

| | Inputs | Outputs |
|---|---|---|
| 1 | Coronal T2 Prostate MRI<br>Transverse T2 Prostate MRI<br>Sagittal T2 Prostate MRI<br>Transverse HBV Prostate MRI<br>Transverse ADC Prostate MRI<br>Clinical Information Prostate MRI | Case-level Cancer Likelihood Prostate MRI<br>Transverse Cancer Detection Map Prostate MRI |



# Methodology

**AI Model**

- 10207 MRI examinations used to train the AI model
- 1000 MRI examinations used to test the AI model

**Comparator**

- 62 Radiologists expert in reading Prostate MRI (20 countries)
  - 400 MRI readings
- Multidisciplinary board
  - 1000 MRI readings

# Methodology

- Primary endpoints
  - Sensitivity
  - Specificity
  - Area under the receiver operating characteristic curve (AUROC) of the AI system in comparison with that of all readers using PI-RADS

- Histopathology and at least 3 years of follow-up were used to establish the reference standard

# Results

- Of 10 207 examinations included from Jan 1, 2012, through Dec 31, 2021, 2440 cases had histologically confirmed Gleason grade group 2 or greater prostate cancer

- In the subset of 400 testing cases in which the AI system was compared with the radiologists
  - the AI system showed a statistically superior and non-inferior AUROC of 0·91 (95% CI 0·87–0·94; p<0·0001)
  - AUROC for pool of 62 radiologist was 0·86 (0·83–0·89)

# Results

- At the mean PI-RADS 3 or greater operating point of all readers, the AI system detected
  - 6·8% more cases with Gleason grade group 2 or greater cancers
  - 50·4% fewer false- positive results and 20·0% fewer cases with Gleason grade group 1 cancers at the same sensitivity

# AI vs Multidisciplinary readings

- In all 1000 testing cases where the AI system was compared with the radiology readings made during multidisciplinary practice, non-inferiority was not confirmed
- AI system showed lower specificity (68·9% [95% CI 65·3–72·4] vs 69·0% [65·5–72·5])

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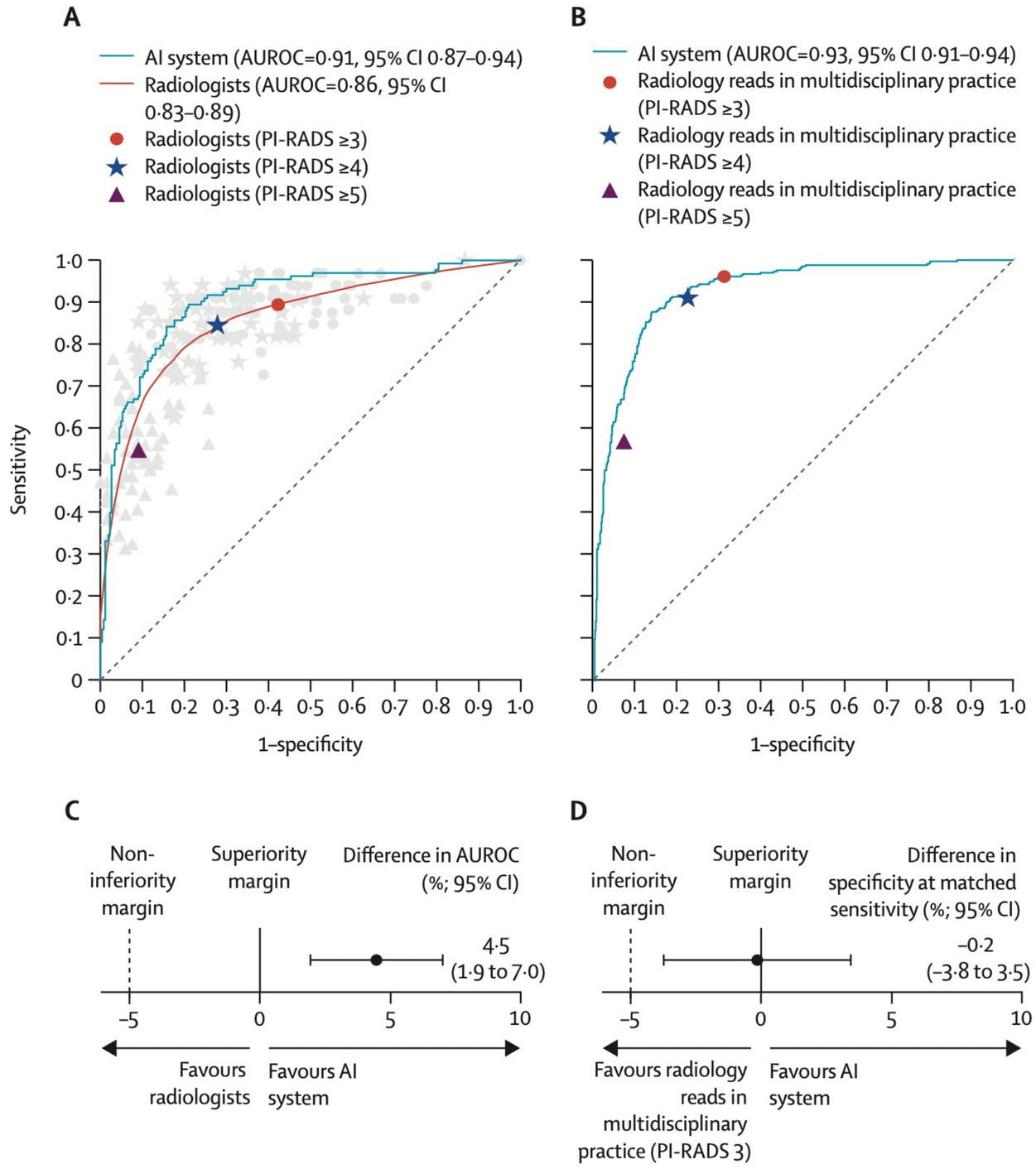

# Conclusion

- AI system was superior to radiologists using PI-RADS (2.1) at detecting clinically significant prostate cancer
- AI was not superior to the MDT detection of prostate cancer (because of incorporation of clinical findings in MDT)
- This study provided evidence that AI systems, when adequately trained, could potentially support the diagnostic pathway of prostate cancer management


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# Prospective Clinical Implementation of Paige Prostate Detect Artificial Intelligence Assistance in the Detection of Prostate Cancer in Prostate Biopsies: CONFIDENT P Trial Implementation of Artficial Intelligence Assistance in Prostate Cancer Detection

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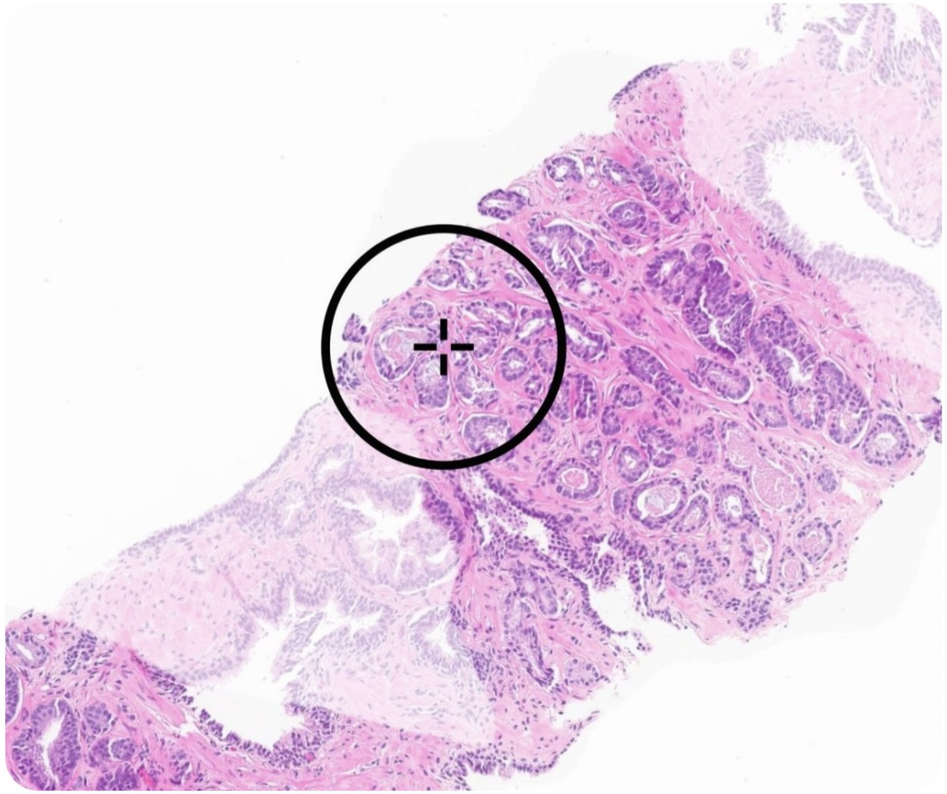

# Paige Prostate

The Paige Prostate Suite is a group of comprehensive AI-powered applications that aid in the detection and grading of prostate cancer on H&E-stained whole-slide images of prostate needle biopsies.

Paige Prostate Detect was the first AI-based software application in pathology to receive **FDA approval** to aid in the primary diagnosis of prostate cancer.[ii]

Paige Prostate Detect[ii]

Assists in the detection of foci suspicious for cancer

Paige Prostate Grade & Quantify[iii]

Paige Prostate Perineural Invasion (PNI)[iii]

**Independent validation studies have shown Paige Prostate Detect to**

- **Enhance Efficiency** - *up to 21.9% reduction in slide evaluation times*[1]
- **Reduce Diagnostic Turnaround Times** – *65.5% reduction in time to diagnosis*[3]
- **Support a Confident Diagnosis** – *70% reduction in diagnostic error*[4]
- **Can reduce the need for IHC and associated cost reduction**[1]

# Prospective Clinical Implementation of Paige Prostate Detect Artificial Intelligence Assistance in the Detection of Prostate Cancer in Prostate Biopsies: CONFIDENT P Trial Implementation of Artificial Intelligence Assistance in Prostate Cancer Detection

Rachel N. Flach, MD, PhD[1,2]; Carmen van Dooijeweert, MD, PhD[1]; Tri Q. Nguyen, MD, PhD[1]; Mitchell Lynch, MD[3]; Trudy N. Jonges, MD, PhD[1]; Richard P. Meijer, MD, PhD[2]; Britt B.M. Suelmann, MD, PhD[4]; Peter-Paul M. Willemse, MD, PhD[2]; Nikolas Stathonikos, MSc[1]; and Paul J. van Diest, MD, PhD[1]

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9:e2400193

# Synopsis

- This prospective clinical trial evaluated whether an AI- assisted workflow for detecting PCa in Prostate Biopsy reduces IHC use while maintaining diagnostic safety standards

- Use of IHC
  - Negative biopsies
  - Doubtful lesions
  - GS 3+3 and 3+4 lesions
  - Distinguish IDC from Cribriform lesions

- P53 : Basal layer stains in normal prostate tissue, lost in malignancy
- AMACR : stains positively in malignant tissue

# Methodology

- Patients suspected of PCa were allocated biweekly to either a control or intervention arm
- Control arm: pathologists assessed whole-slide images (WSI) of PBx using HE and IHC staining
- Intervention arm : pathologists used the Paige Prostate Detect AI algorithm on HE slides, requesting IHC only as needed

# AI model : Paige Prostate Detect Artificial Intelligence

- PPD-AI is a convolutional neural network trained on 32,341 cases from 6,775 patients at Memorial Sloan Kettering Cancer Center (MSKCC) in New York, and 44 international laboratories

- The output is a binary prediction (benign or suspicious), highlighting regions with the highest likelihood of harboring cancer

# Study Design

- This two-arm interventional trial (ISRCTN: 14323711) alternated PBx samples biweekly between the control arm and the AI arm

- In the control arm, pathologists assessed HE slides, with IHC available from the start, according to the standard workflow

- In the AI arm, deidentified HE-WSI were uploaded for PPD- AI analysis before pathologist review, with IHC requested if needed. If no tumor was detected, or in case of uncertainty about the diagnosis, additional IHC was performed

# Study endpoint

- Primary end point was the RR of IHC use per detected PCa case (both on patient level and slide level)
- Secondary endpoint :
  - Time spent per WSI
  - Absolute reduction of IHC stains and associated costs
  - Pathologist confidence in diagnosis on HE slides, rated on a five-tier confidence level (no confidence to high confidence)

# Results

- 109 slides in AI arm; 130 slides in control arm
- IHC used on all slides in Control Arm
- IHC used in 75/109 (68.8%) slides in AI arm
- Reasons for IHC use in AI arm
  - 37/75 slides : benign
  - 19/75 slides : uncertain
  - 19/75 slides : differentiate cribriform growth from intraductal carcinoma

# Results

- AI reduced the RR of IHC use on both patient level (RR, 0.55 [95% CI, 0.39 to 0.72]) and.
  - Patient level : RR : 0.55 [95% CI, 0.39 to 0.72]
  - Slide level : RR : 0.41 [95% CI, 0.29 to 0.53]
- Cost reductions
  - 34 slides did not need IHC due to AI
  - 34 x 50 Euros : 1700 Euros

# Results

- Pathologists’ performance
  - Pathologists’ confidence levels on HE-WSI were higher in the AI arm than in the control arm, with almost 80% of slides signed out at a confident or high confidence level, compared with just over half in the control arm (P < .001).

# Conclusion

- AI assisted pathological reading reduces the need for IHC
  - Improves efficiency
  - Quicker reporting
  - Decreases financial burden of IHC
- AI assistance improves the sensitivity and Negative Predictive Value of pathologists' reporting

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**Original Reports** | Pathology

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MAX Healthcare

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# Thank you