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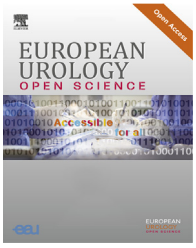

European Association of Urology

Prostate Cancer

Evaluating Diagnostic Accuracy and Inter-reader Agreement of the Prostate Imaging After Focal Ablation Scoring System

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Abstract

Background and objective: Focal therapy (FT) is increasingly recognized as a promising approach for managing localized prostate cancer (PCa), notably reducing treatment-related morbidities. However, post-treatment anatomical changes present significant challenges for surveillance using current imaging techniques. This study aimed to evaluate the inter-reader agreement and efficacy of the Prostate Imaging after Focal Ablation (PI-FAB) scoring system in detecting clinically significant prostate cancer (csPCa) on post-FT multiparametric magnetic resonance imaging (mpMRI).

Methods: A retrospective cohort study was conducted involving patients who underwent primary FT for localized csPCa between 2013 and 2023, followed by post-FT mpMRI and a prostate biopsy. Two expert genitourinary radiologists retrospectively evaluated post-FT mpMRI using PI-FAB. The key measures included inter-reader agreement of PI-FAB scores, assessed by quadratic weighted Cohen's kappa (κ), and the system's efficacy in predicting in-field recurrence of csPCa, with a PI-FAB score cutoff of 3. Additional diagnostic metrics including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were also evaluated.

Key findings and limitations: Scans from 38 patients were analyzed, revealing a moderate level of agreement in PI-FAB scoring (κ = 0.56). Both radiologists achieved sensitivity of 93% in detecting csPCa, although specificity, PPVs, NPVs, and accuracy varied.

Conclusions and clinical implications: The PI-FAB scoring system exhibited high sensitivity with moderate inter-reader agreement in detecting in-field recurrence of

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csPCa. Despite promising results, its low specificity and PPV necessitate further refinement. These findings underscore the need for larger studies to validate the clinical utility of PI-FAB, potentially aiding in standardizing post-treatment surveillance.

Patient summary: Focal therapy has emerged as a promising approach for managing localized prostate cancer, but limitations in current imaging techniques present significant challenges for post-treatment surveillance. The Prostate Imaging after Focal Ablation (PI-FAB) scoring system showed high sensitivity for detecting in-field recurrence of clinically significant prostate cancer. However, its low specificity and positive predictive value necessitate further refinement. Larger, more comprehensive studies are needed to fully validate its clinical utility.

1. Introduction

Focal therapy (FT), which involves the targeted destruction of prostate cancer (PCa) tissue while preserving the rest of the prostate gland, has emerged as a promising management strategy for localized PCa. FT offers a compelling alternative to conventional treatments such as radiation or radical surgery and is an active area of investigation [1–4]. Its proposed advantage lies in achieving adequate oncological control while reducing treatment-related morbidities, especially erectile dysfunction and urinary incontinence [2,5]. However, despite increased utilization and interest in FT, challenges remain regarding post-treatment surveillance, primarily due to limitations in current imaging techniques [6].

The integration of multiparametric magnetic resonance imaging (mpMRI) into PCa management has been transformative, particularly in tumor localization and biopsy guidance, facilitating the adoption and refinement of FT [7,8]. In the post-FT setting, however, the utility of mpMRI may be limited [9–11]. Treatment-induced distortion of prostate anatomy can obscure and complicate the interpretation of mpMRI, posing difficulties in assessing treatment efficacy and detecting potential recurrences [12–14]. This underscores the necessity for a more robust, standardized imaging assessment guideline for postablation evaluation.

To bridge this gap, the Prostate Imaging after Focal Ablation (PI-FAB) scoring system was developed recently [15]. PI-FAB is a novel three-point scoring system applied to post-FT mpMRI scans that aims to standardize the assessment of intraprostatic lesions. It assesses the three mpMRI sequences starting with the contrast-enhanced sequence, which is most relevant in this setting. For patients with a PI-FAB score of 1, monitoring may be continued. For a PI-FAB score of 2, prostate-specific antigen (PSA) kinetics may be assessed and a biopsy is considered if PSA is rising. For a PI-FAB score of 3, a biopsy is recommended. Since this scoring system is new, it has yet to undergo external validation in diverse patient cohorts. Our study aims to deploy PI-FAB in a cohort of post-FT patients and evaluate its efficacy and inter-reader agreement for the detection of clinically significant prostate cancer (csPCa) in post-FT mpMRI evaluation.

2. Patients and methods

2.1. Patient population

This retrospective study included patients who underwent primary FT for localized csPCa and subsequent follow-up, including post-FT mpMRI and a prostate biopsy, at a single institution between 2013 and 2023. FT modalities that patients received included focal laser ablation (FLA), high-intensity focused ultrasound (HIFU), and cryoablation. FLA procedures were conducted in our institution under institutional review board (IRB)-approved clinical trials (NCT01377753 and NCT02759744), whereas HIFU and cryoablation patients were referred to our center for further workup of suspicion of recurrence. In patients who underwent multiple rounds of FT treatment, images after the final FT session were included.

2.2. MRI technique and prostate biopsy

All patients underwent prostate mpMRI following FT, either as part of a normal surveillance regimen or due to clinical factors elevating the risk of recurrence. Images were obtained according to Prostate Imaging Reporting and Data System (PI-RADS) v2.1 recommendation for mpMRI acquisition at various time points after FT. Time from FT to post-FT MRI was recorded based on MRI dates. Scans for patients prior to approximately 2018 were obtained at 3 Tesla using an endorectal coil and a 16-channel phased array surface coil. T1-weighted (T1W) MRI, T2-weighted (T2W) MRI, apparent diffusion coefficient (ADC) maps, and diffusion-weighted (DW) MRI with a b value of 2000 s/mm^2 were obtained in these patients. In more recent patients, an endorectal coil was not used during mpMRI, and scans were obtained at 3 Tesla using a 32-channel phased array surface coil. T1W MRI, T2W MRI, ADC maps, and DW MRI with a b value of 1500 s/mm^2 were obtained. Dynamic contrast-enhanced (DCE) MRI of the prostate utilizing gadoterate meglumine intravenous injection along with axial postcontrast T1W MRI of the abdomen was obtained for all patients in this cohort. Prospective clinical MRI evaluations at the time of initial imaging were done by one experienced genitourinary radiologist. The prospectively detected recurrent lesions after FT as well as patients without a suspicion of

recurrence were biopsied transrectally by an expert urologist (P.A.P. with 18 yr of experience) using a commercial MRI/transrectal ultrasound (TRUS) fusion system (UroNav; Philips). Additionally, a standard 12-core biopsy was performed, with all samples tracked by the same biopsy guidance system for future reference. Biopsy specimens were evaluated by one expert genitourinary pathologist (M.J.M. with >30 yr of experience) using the Gleason grading (GG) system.

2.3. PI-FAB scoring

MRI scans were retrospectively evaluated by two expert genitourinary radiologists (B.T. with 16 yr of experience and 1000 prostate MRI scans per year, and Y.M.L. with 9 yr of experience and 1000 prostate MRI scans per year) independently using the PI-FAB scoring system, as proposed by Giganti et al [15]. The radiologists received anonymized patient images and were provided patient ages, serum PSA values, locations of the FT-treated lesion(s) when available, and the FT modality, but were blinded to biopsy pathology results. Readers assigned one PI-FAB score ranging from 1 to 3 for each case, and indicated the region of ablation. Figures 1 and 2 demonstrate mpMRI scans from one PI-FAB 3 patient before- and after FLA, respectively. An additional PI-FAB 1 case is provided in the Supplementary material. In cases where there were multiple ablated zones, the area with the highest PI-FAB score was used.

2.4. Data collection and statistical analysis

This study involved the use of patient charts and MRI images retrospectively obtained from an IRB-approved clinical trial evaluating the use of MRI in PCa diagnosis (NCT03354416). All procedures adhered to ethical guidelines for patient confidentiality and data handling. PI-FAB scores were recorded for each radiologist. Demographic and clinical data were extracted from our institution's electronic medical record system and listed using descriptive statistics. Inter-reader agreement of the PI-FAB scoring system was assessed using the quadratic weighted Cohen's kappa (κ), which evaluates the level of agreement between the two radiologists' interpretations of the mpMRI scans. Diagnostic performance metrics for each reader were calculated to assess the accuracy of PI-FAB in predicting in-field recurrence of csPCa (defined as Gleason grade group $\geq$2 disease identified at a previously ablated site on prostate biopsy) using a PI-FAB score cutoff of 3. A statistical analysis was performed in GraphPad Prism (version 10.0.02, 2023; GraphPad Software, Boston, MA, USA) and R statistical software (version 4.2.2; R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Patient population and cohort demographics

A total of 38 patients who underwent primary FT for the treatment of localized PCa were included in this study. The distribution of FT modalities among these patients was as follows: 28 patients (74%) received FLA, six patients (16%) underwent HIFU, and four patients (11%) had cryoablation. The number of rounds of FT prior to MRI varied, with 31 patients (82%) having undergone only one round, five patients (13%) two rounds, one patient (3%) three rounds, and one patient (3%) four rounds. The median patient age at the time of post-FT MRI was 69.5 yr (interquartile range [IQR], 64.8–75), and the median post-FT serum PSA at the time of MRI was 4.9 ng/ml (IQR, 2.2–8.2) across the cohort. The median time to post-FT MRI used for the PI-FAB analysis was 2.5 yr (IQR, 1.4, 4.9). More than half of the patients (22, 58%) had endorectal coils used during their MRI scans. Patient demographics separated by FT modality are detailed in Table 1.

3.2. Inter-reader agreement

The inter-reader agreement for PI-FAB was assessed between the two expert genitourinary radiologists. The distribution of PI-FAB scores for reader 1 was as follows: 15 scans (39%) scored 1, one scan (3%) scored 2, and 22 scans (58%) scored 3. Similarly, for reader 2, the distribution was as follows: ten scans (26%) scored 1, four scans (11%) scored 2, and 24 scans (63%) scored 3. A heatmap of these PI-FAB scores, offering a visual representation of the scoring distribution between the two readers is displayed in Figure 3. The quadratic weighted Cohen's kappa indicated a moderate level of agreement between both readers (κ = 0.56).

3.3. Diagnostic performance metrics

For reader 1, the sensitivity for detecting csPCa using a PI-FAB score cutoff of 3 was 92.9% (13/14), with specificity of 62.5% (15/24). The positive predictive value (PPV) was calculated as 59.1% (13/22), and the negative predictive value (NPV) was 93.8% (15/16). Overall accuracy was 73.7% (28/38). For reader 2, sensitivity was also 92.9% (13/14), with specificity of 54.2% (13/24). The PPV was 54.2% (13/24) and the NPV was 92.9% (13/14). The overall accuracy was 68.4% (26/38). These metrics are shown in Table 2. Both readers each missed one in-field csPCa case of recurrence using PI-FAB, equating to a false negative rate of 7.1% (1/14).

4. Discussion

Our study highlights the use of the PI-FAB scoring system in detecting post-treatment csPCa, demonstrating per-patient sensitivity exceeding 90% across various FT modalities. Notably, this multireader study indicates a moderate level of inter-reader agreement between genitourinary radiologists.

This study is among the first to externally validate the utility of the newly introduced PI-FAB system. The high sensitivity of PI-FAB is encouraging, given previously documented low sensitivity of MRI for csPCa of MRI in the post-FT setting. Although PI-FAB is new and has not been through extensive external validation, post-FT imaging is a relatively commonly investigated topic. Lepor et al [9] reported mpMRI sensitivity for recurrent csPCa of 38% in the postcryotherapy setting. Similarly, without the

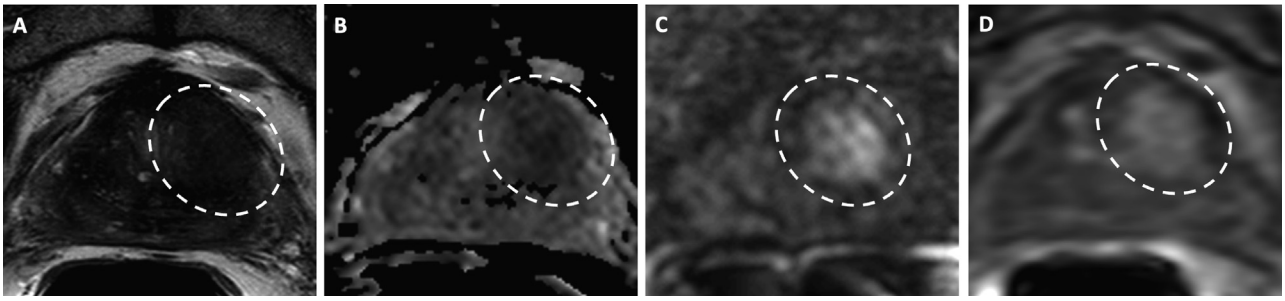

Fig. 1 – Pretreatment multiparametric MRI of a 54-yr-old patient with a serum PSA level of 15.44 ng/ml. Axial T2W MRI shows a homogenously hypointense lesion in the left base anterior transition zone (dotted circle) on (A) T2W MRI, (B) apparent diffusion coefficient map, (C) high *b* value (*b* = 2000 s/mm^2) diffusion-weighted MRI, and (D) dynamic contrast-enhanced MRI, which demonstrates early contrast enhancement, and diffusion restriction, which reveals a PI-RADS score of 5. A slight capsular bulge is present with no direct extraprostatic extension. MRI = magnetic resonance imaging; PI-RADS = Prostate Imaging Reporting and Data System; PSA = prostate-specific antigen; T2W = T2 weighted.

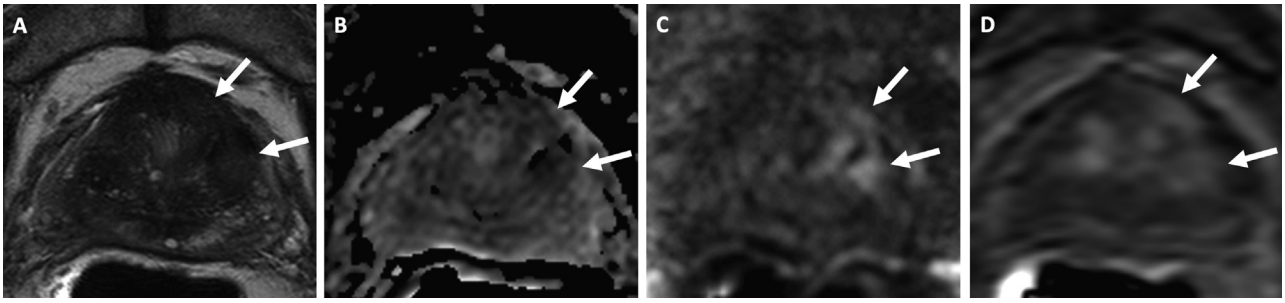

Fig. 2 – Post-treatment multiparametric MRI of the same patient at age 56, approximately 1 yr status after focal laser ablation with a serum PSA level of 15.27 ng/ml. The inferior portion of the treated lesion shows stable cystic changes, whereas the superior portion (arrows) is positive on (A) T2W MRI, (B) apparent-diffusion coefficient maps, (C) high *b* value (*b* = 2000 s/mm^2) diffusion-weighted MRI, and (D) dynamic contrast-enhanced MRI revealing a PI-FAB score of 3. An MRI/TRUS fusion–guided biopsy of this lesion demonstrated Gleason grade group 2 prostate cancer. MRI = magnetic resonance imaging; PI-FAB = Prostate Imaging after Focal Ablation; PSA = prostate-specific antigen; TRUS = transrectal ultrasound; T2W = T2 weighted.

Table 1 – Patient demographics by focal therapy

Variable	Overall (*N* = 38)	FLA (*N* = 28)	HIFU (*N* = 6)	Cryoablation (*N* = 4)
Age at MRI (yr)	69.5 (64.8, 75)	68.5 (65.3, 73)	73 (61.5, 76.3)	70.5 (63, 76)
PSA (ng/ml)	4.9 (2.2, 8.5)	4.9 (2.9, 8.3)	4.0 (1.1, 9.7)	6.3 (1.5, 13.2)
Time to MRI after FT (yr)	2.5 (1.3, 5.2)	2.0 (1.0, 3.8)	4.5 (2.5, 11.0)	5.2 (2.7, 13.8)

FLA = focal laser ablation; FT = focal therapy; HIFU = high-intensity focused ultrasound; MRI = magnetic resonance imaging; PSA = prostate-specific antigen. Continuous variables are represented as median and interquartile range (Q1, Q3).

standardization of the PI-FAB system, Aker et al [16] showed that post-FT MRI findings did not correlate with final biopsy pathology after FT. In the HIFU literature, only limited data exist. Dickinson et al [17] analyzed 118 patients who underwent focal HIFU and reported sensitivity of mpMRI between 63% and 80% for detecting csPCa at a time point of 6 mo following HIFU FT.

The optimal follow-up time points for post-FT imaging and biopsy are still not well established. MRI findings continue to evolve over time after FT [17], regardless of ablation modality as the tissue heals. Our study includes patients who had spent at least 6 mo after FT, but follow-up ranged up to 5 yr after FT. The relatively high NPV noted among readers calls into question the need for routine per-protocol post-FT biopsies. At present, this practice has become routine due to the low NPV of MRI for residual/recurrent disease in the post-FT setting. Low PI-FAB scores can effectively rule out the in-field recurrence of csPCa, potentially reducing the frequency of biopsies for patients. However, given the novelty of the PI-FAB system, a comprehensive clinical assessment, including PSA kinetics and patient history, remains crucial in guiding treatment decisions.

Our study reveals a tradeoff between high sensitivity and relatively lower specificity and PPV. While lower specificity and PPV might typically raise concerns about overdiagnosis and unnecessary biopsies, it is essential to consider the unique context of this patient population. Given the investigational nature of FT and the potential for high-risk csPCa recurrence, early detection and appropriate treatment of recurrent disease is critical. A highly sensitive screening tool becomes invaluable for these patients, as it markedly increases the chances of identifying recurrent, in-field csPCa. Although the incidence of medium-term events after

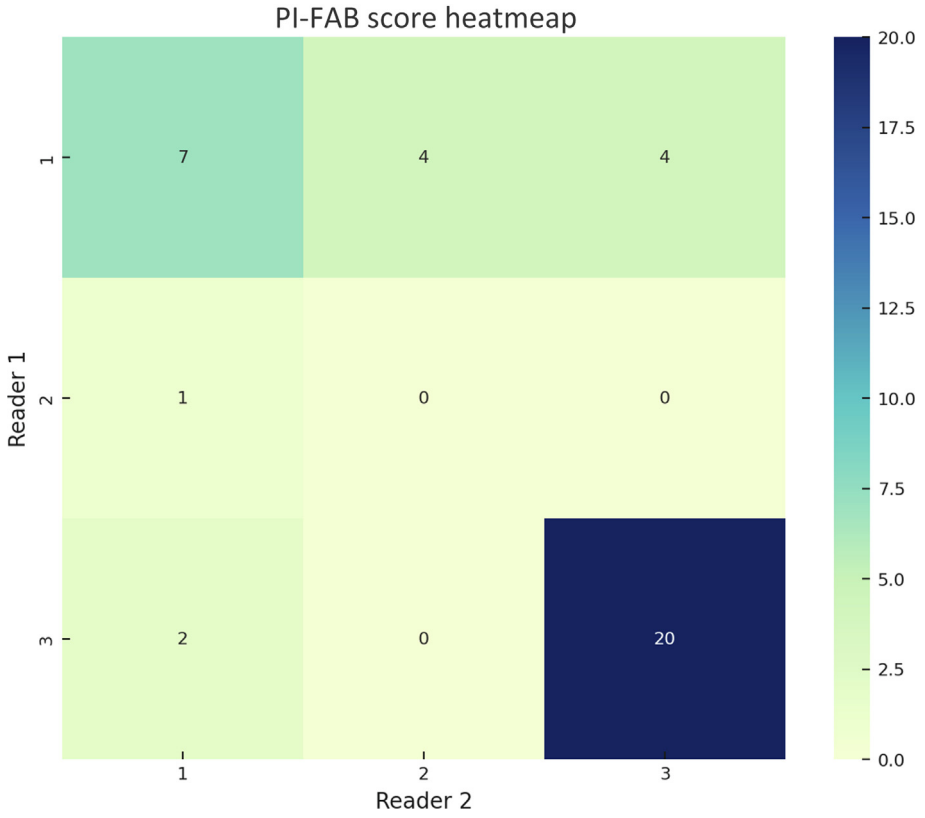

Fig. 3 – Heatmap of visualization of PI-FAB scores assigned by both readers. Each row/column corresponds to one of three possible PI-FAB scores. The intensity of the color in each cell reflects the frequency of agreement in scores between both readers. This allows for visualization of areas where readers' assessments converge or diverge, illustrating inter-reader agreement of the PI-FAB scoring system. PI-FAB = Prostate Imaging after Focal Ablation.

Table 2 – Performance metrics for both readers for detecting in-field recurrence of csPCa given a PI-FAB cutoff of 3

Performance metric	Reader 1 (%)	Reader 2 (%)
Sensitivity	92.9 (13/14)	92.9 (13/14)
Specificity	62.5 (15/24)	54.2 (13/24)
PPV	59.1 (13/22)	54.2 (13/24)
NPV	93.8 (15/16)	92.9 (13/14)
Accuracy	73.7 (28/38)	68.4 (26/38)

csPCa = clinically significant prostate cancer; NPV = negative predictive value; PI-FAB = Prostate Imaging after Focal Ablation; PPV = positive predictive value.

FT such as the onset of metastatic disease is reportedly low [18], little is known about the long-term oncological outcomes of those who experience csPCa recurrence after FT. We know that patients with localized csPCa are at a higher risk of metastasis and long-term PCa-specific mortality than patients with GG1 tumors [19], and in managing post-FT patients, prioritizing sensitivity may be justified to facilitate thorough monitoring and prompt intervention of recurrent PCa. While this approach could result in more frequent biopsies, the benefit of early and accurate detection of recurrence might outweigh the risks associated with these additional interventions. Further research is necessary to determine long-term risks of metastasis and PCa-specific mortality in this population, compared with treatment-naïve patients.

A critical aspect of this study was the examination of inter-reader agreement in the application of PI-FAB. Interobserver agreement is a well-recognized challenge in radiology, reflecting the complex and subjective nature of image interpretation when structured scoring systems are utilized [20]. It is known that increased experience contributes to improved agreement, especially in systems such as the PI-RADS [21,22]. Our findings demonstrate a moderate level of agreement (κ = 0.56) between two expert genitourinary radiologists. This level of concordance is notable considering that neither had prior clinical experience with PI-FAB prior to taking part in this study. This outcome aligns with more established image reporting systems in the field, such as Prostate Imaging Quality (PI-QUAL) and PI-RADS, where similar levels of inter-reader agreement have been documented, but performance improved with time [23–25]. The agreement observed in our study reflects the inherent challenges in standardizing new diagnostic tools and underscores the potential for improved consistency as PI-FAB is used over time. Thus, larger studies comparing radiologists of varying experience levels will be important in validating PI-FAB.

This study uncovered some limitations of PI-FAB. This scoring system was created by one group without following a proper consensus process during development. Another significant drawback of this system is its heavy reliance on DCE MRI, which is not universally available in all clinical settings. This dependency may restrict the applicability of PI-FAB in institutions where DCE MRI is less frequently used or unavailable. Furthermore, the PI-FAB system does not

account for instances where the precise location of previously ablated tissue is unknown, which can be a common scenario in high-volume imaging centers where prior treatment information may be hard to obtain. Here, we employed PI-FAB for grading a risk of in-field recurrence with full knowledge of the treatment site, but it is not clear how PI-FAB or even PI-RADS could be utilized to score the untreated portions of the gland. Additionally, PI-FAB lacks certain score combinations, such as scenarios where T2W imaging or ADC maps are negative, leaving outcomes without a clear scoring pathway. Our study also has limitations worth mentioning. In-field recurrence evaluation was mainly based on MRI/TRUS targeted biopsies but required the use of systematic 12-core biopsies in some cases. All patients underwent 12-core systematic biopsies where prostate gland integrity was preserved. Additionally, only one post-treatment scan was evaluated for each patient. The retrospective nature, focus on a single institutional cohort, and inclusion of a small number of patients may also limit the generalizability of these findings. Additionally, the novelty of this system implies a possible learning curve, and more practice cases are required to fully adapt to this new tool. This suggests the need for further research on a larger scale, involving multiple centers, and prospective studies to validate and refine PI-FAB in a more diverse and representative patient population as more radiologists gain familiarity and expertise with its application.

5. Conclusions

This study's evaluation of the PI-FAB scoring system in our post-FT patient cohort offers crucial insights into its diagnostic accuracy and inter-reader agreement among different radiologists. The moderate agreement between two expert radiologists and high sensitivity in detecting in-field recurrence of csPCa underscore the potential value of PI-FAB in post-FT assessment and surveillance. However, the relatively low specificity and PPV, ambiguous scoring combinations, and large reliance on DCE MRI highlight the need for further refinement of the system. Larger studies are needed to fully validate its clinical utility, but as advancements continue to be made in FT PCa treatment, tools such as PI-FAB will be pivotal in enhancing accuracy and standardization of post-treatment evaluation, contributing to better patient outcomes and care.

***Author contributions*:** Baris Turkbey 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: Gelikman, Kenigsberg, Merino, Gurram, Choyke, Wood, Pinto, Turkbey.
Acquisition of data: Gelikman, Kenigsberg, Law, Yilmaz, Harmon, Merino, Choyke, Wood, Pinto, Turkbey.
Analysis and interpretation of data: Gelikman, Kenigsberg, Yilmaz, Parikh, Hyman, Huth, Koller, Nethala, Hesswani.
Drafting of the manuscript: Gelikman, Kenigsberg.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Gelikman, Kenigsberg, Harmon.
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Appendix A. Supplementary data

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