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MRI-based monitoring of prostate cancer after HIFU: Inter-reader agreement and diagnostic performance of the PI-FAB score

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ABSTRACT

Purpose: To investigate inter-reader agreement, and diagnostic performance of the Prostate Imaging after Focal Ablation (PI-FAB) score applied to multiparametric MRI (mpMRI) in patients who underwent focal high-intensity focused ultrasound (HIFU) therapy for localized prostate cancer.

Methods: In this retrospective, IRB-approved, single-center study, 73 men, who underwent focal HIFU treatment and received follow-up mpMRIs with subsequent prostate biopsies, were included. The PI-FAB score was applied to follow-up MRIs at 6, 12, and 36 months post-HIFU by two radiologists with different experience levels. Inter-reader agreement was assessed using Gwet's AC1, and the diagnostic performance of the PI-FAB score was assessed in relation to histopathologic results of subsequent prostate biopsies for each reader.

Results: PI-FAB scores showed substantial to almost perfect inter-reader agreement (AC1: 0.80–0.95) and demonstrated high specificity (Reader 1: 90–98 %, Reader 2: 87–98 %) and NPVs (Reader 1: 91–100 %, Reader 2: 88–97 %) in ruling out residual or recurrent in-field prostate cancer post-HIFU. Sensitivity (Reader 1: ≥43 %, Reader 2: ≥14 %) and PPVs (Reader 1: ≥33 %, Reader 2: ≥14 %) were mostly relatively lower, with notable disparities between the two readers, indicating the potential influence of radiologist experience.

Conclusions: The PI-FAB score provides a consistent and reliable tool for post-HIFU monitoring of prostate cancer using mpMRI. It demonstrates substantial to almost perfect inter-reader agreement and is particularly effective in excluding in-field residual or recurrent prostate cancer post-HIFU treatment. Its application can potentially enhance post-treatment patient care, emphasizing its value as a non-invasive MRI-based monitoring approach after focal ablative therapy of the prostate.

1. Introduction

Current therapeutic options for localized prostate cancer include watchful waiting, active surveillance, radiation therapy and radical prostatectomy [1]. As most men are diagnosed with prostate cancer at an early, localized stage, there is an increasing awareness of the risks of over-treatment [1,2]. Focal therapy for prostate cancer (PCa) encompasses a set of minimally invasive procedures aimed at selectively destroying a localized area of PCa while preserving the surrounding non-cancerous tissue [3]. Consequently, focal ablation emerges as a viable alternative for patients with localized disease requiring active treatment, as it allows for a targeted tumor control while sparing the adjacent healthy tissue, thereby minimizing potential adverse events such as urinary incontinence, erectile dysfunction or proctitis [4].

However, conventional postinterventional monitoring using prostate-specific antigen (PSA) levels poses challenges after focal therapy due to varying amounts of residual viable prostate tissue after treatment [5]. Furthermore, consecutive post-treatment prostate biopsies are invasive and carry potential morbidity, along with the risk of undersampling and undergrading, particularly in small tumor foci and when non-targeted [5,6]. Multiparametric magnetic resonance imaging (mpMRI) has become an integral component in the context of focal therapy, serving not only for treatment planning but also for post-interventional monitoring [3,6]. Common MR-morphologic changes of the ablated prostate have already been well studied in literature [6–9]. However, there is still a need to identify specific imaging characteristics

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Table 1
Overview of patient characteristics outlining demographics and different scores.

Patient characteristics (n = 73)	
Age in years, median (IQR)	66 (61–70)
PSA pre-HIFU in ng/ml, median (IQR)	6.0 (4.5–7.6)
Highest PI-RADS score pre-HIFU, n (%)	
PI-RADS 2	6 (8.2)
PI-RADS 3	6 (8.2)
PI-RADS 4	33 (45.2)
PI-RADS 5	28 (38.4)
Highest Gleason score pre-HIFU, n (%)	
Gleason 3 + 3 (ISUP/WHO grade 1)	4 (5.5)
Gleason 3 + 4 (ISUP/WHO grade 2)	50 (68.5)
Gleason 4 + 3 (ISUP/WHO grade 3)	19 (26.0)

PSA: prostate specific antigen, PI-RADS: Prostate Imaging Reporting and Data System, HIFU: high-intensity focused ultrasound, ISUP/WHO: International Society of Urological Pathology/World Health Organization.

Table 2
Overview of PSA levels, ISUP/WHO grade groups, PI-FAB scores from both readers, and the applied management strategies for cases involving in-field residual or recurrent prostate cancer at the different time points of follow-up after HIFU therapy.

Time point of follow-up	Case	PSA in ng/ml	ISUP/WHO GG	PI-FAB score (R 1)	PI-FAB score (R 2)	Management strategy
6 m post-HIFU	1	7.69	2	1	1	AS*
	2	1.54	2	3	1	Re-HIFU
	3	2.24	2	1	1	Re-HIFU
	4	0.94	2	1	1	RPE
	5	0.62	4	1	1	AS*
	6	2.52	4	3	1	Re-HIFU
	7	3.22	4	3	3	RPE
12 m post-HIFU	1	2.04	2	3	1	AS*
	2	3.99	2	1	1	RPE
	3	2.86	2	2	1	Re-HIFU
	4	3.88	2	1	1	Re-HIFU
	5	2.81	3	3	3	Re-HIFU
	6	2.78	3	1	1	Re-HIFU
	7	0.91	4	1	1	AS*
36 m post-HIFU	1	10.01	3	3	1	RPE
	2	4.60	4	3	3	AS*

R 1: Reader 1/experienced reader. R 2: Reader 2/less experienced reader. ISUP/WHO GG: International Society of Urological Pathology/World Health Organization grade group. AS*: active surveillance due to high patient age, poor general health condition and/or low tumor volume. Re-HIFU: repeated high-intensity focused ultrasound therapy. RPE: radical prostatectomy. m: months.

for reliably detecting or ruling out residual or recurrent prostate cancer after focal therapy and to establish a standardized methodology for monitoring.

Recently, Giganti et al. [10] introduced the Prostate Imaging after Focal Ablation (PI-FAB) score to evaluate the prostate after focal ablation of localized prostate cancer, which is based on visual assessment of distinct MR-imaging features potentially indicative of residual or recurrent in-field prostate cancer and constitutes the first score for post-ablative MRI-monitoring. The objective of our study was to retrospectively explore the PI-FAB score in a cohort of patients who underwent focal high-intensity focused ultrasound (HIFU) therapy. We aimed to assess inter-reader agreement, and diagnostic performance of this scoring method following HIFU treatment.

2. Methods

2.1. Study design and standard-of-reference

This retrospective, institutional review board-approved single-center study, included consecutive patients aged 18 years or older who underwent focal HIFU therapy between April 2014 and April 2019 and had baseline mpMRIs available prior to their treatment. These patients had been selected for HIFU treatment based on specific criteria: low- to intermediate-risk non-metastatic prostate cancer, characterized by a PSA level of 15 ng/ml or lower, International Society of Urological Pathology/World Health Organization (ISUP/WHO) grade group 3 or less, and clinical stage T2 or less, allowing for up to two PCa lesions within these specified conditions. While active surveillance was the primary recommendation for patients with ISUP/WHO grade group 1, a small number of these patients opted for HIFU treatment based on personal preferences.

We identified follow-up mpMRIs conducted at 6, 12, and 36 months following HIFU therapy, as well as histopathological results of subsequent saturation biopsies in combination with targeted biopsies from the ablation zone and, if applicable, any suspicious lesions seen on follow-up mpMRI in clinical routine. Only patients with available follow-up mpMRIs and histopathological biopsy results were included, as a stringent biopsy protocol had been applied. If this requirement was not fulfilled, for example, due to declined MRI or biopsy by the patient, or if radical prostatectomy was performed in the meantime, then the patient was excluded. The histopathological biopsy results constituted the standard-of-reference. A lesion with a Gleason score of $\geq 3 + 4$ (ISUP/WHO grade group ≥ 2) was categorized as "clinically significant cancer" (csPCa) [1]. Furthermore, data concerning age and PSA levels was extracted from our clinical and radiology information systems.

2.2. Multiparametric prostate MRI

MRI examinations were performed on 3.0 Tesla MR scanners (MAGNETOM Skyra, Siemens Healthineers, Erlangen, Germany), adhering to a dedicated multiparametric prostate MRI protocol that aligned with the current Prostate Imaging Reporting and Data System (PI-RADS) guidelines [11] upon scan acquisition, occasionally utilizing endorectal coils as well. The protocol included high-resolution T2-weighted TSE sequences in three planes, diffusion-weighted imaging (with b-values of 100, 600, and 1000 s/mm^2, and a calculated b-value of 1400 s/mm^2), and dynamic contrast-enhanced MRI. For the contrast-enhanced portion, gadoterate meglumine (Dotarem, Guerbet, Villepinte, France) was used as a contrast agent, administered at a dosage of 0.1 mmol/kg body weight.

Two radiologists, one with 4 years (Reader 1, 300 prostate MRIs/year) and the other with 1 year (Reader 2, 250 prostate MRIs/year) of experience in reading prostate MRIs, independently examined the MR images and assigned a PI-FAB score [10] on a Picture Archiving and Communication System (PACS) workstation. Both readers were blinded to all clinical or histopathological details, except for the knowledge that the MRI was conducted for follow-up after HIFU treatment, and had access to the preprocedural baseline MRI for comparison. To ensure consistency and competence, a preparatory training session was conducted before the image analysis, utilizing cases that were not part of the study cohort.

To assess local residuum or local recurrence of prostate cancer on mpMRI following focal ablation, the PI-FAB score [10] uses a 3-point scale analyzing dynamic contrast-enhanced sequences (DCE), diffusion-weighted imaging (DWI/high b-value sequence), and T2-weighted imaging (T2-WI):

PI-FAB 1: Indicated by low signal intensity on both T2-WI and DWI, without enhancement at the original tumor site, suggesting fibrosis. A linear enhancing area not at the original tumor site or ablation cavity edge, likely representing a vessel or inflammation, also falls under this

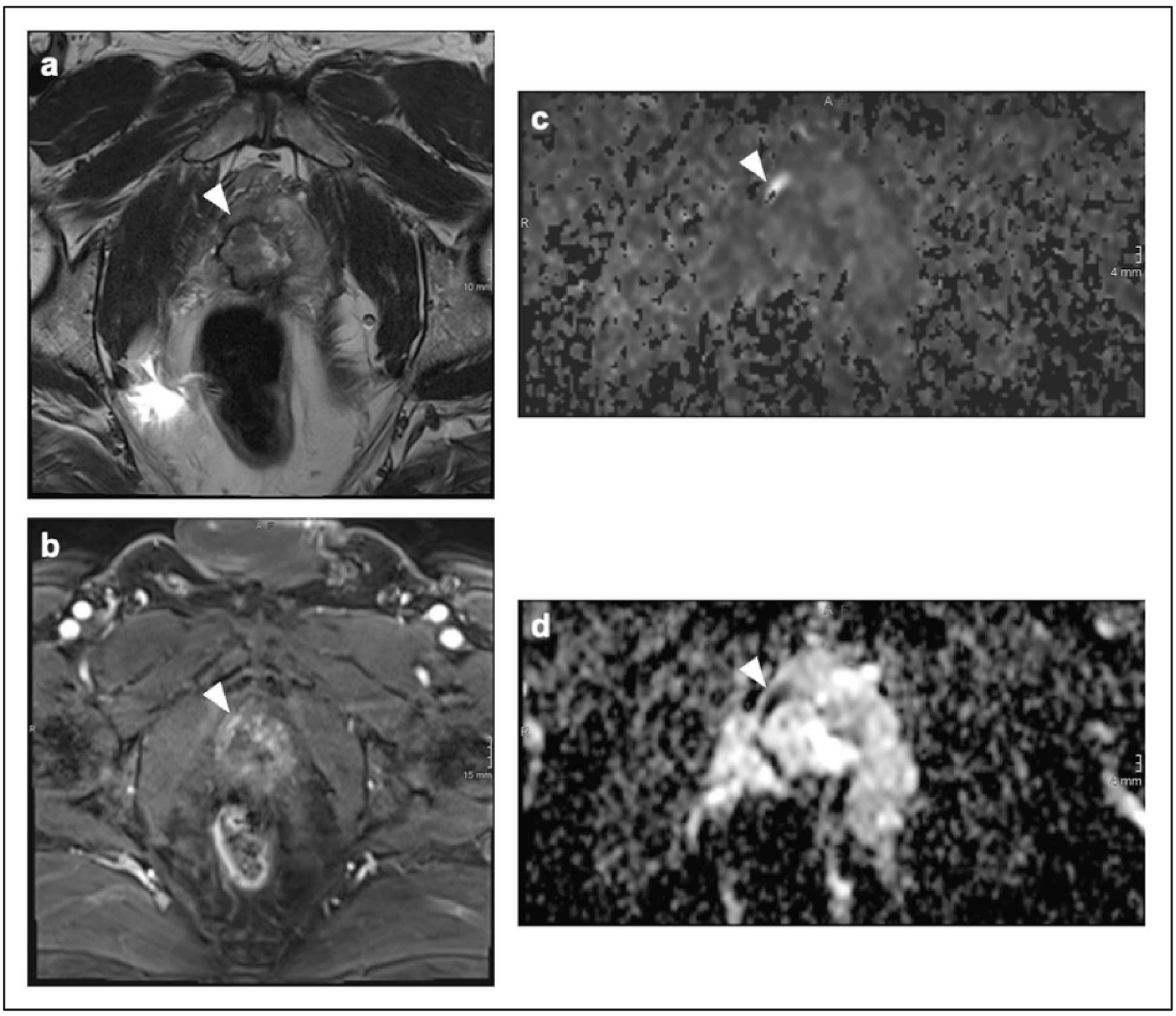

Fig. 1. Multiparametric MRI 6 months after focal HIFU treatment of prostate cancer in the right midglandular prostate. Suspicious lesion with low signal intensity on T2w-imaging (arrowhead in a), diffusion restriction (arrowheads in c/d) and focal enhancement (arrowhead in b) at the anterior border of the ablation zone in the midglandular right anterior peripheral zone, classified as PI-FAB 3. Subsequent biopsy in combination with histopathology revealed a clinically significant prostate cancer (Gleason score 4 + 4, ISUP/WHO grade group 4), most likely due to a local tumor residuum. PSA dynamics were as follows (in ng/ml): 6.09 (pre-HIFU); 1.64 (1.5 months post-HIFU); 2.52 (6 months post-HIFU).

category.

PI-FAB 2: Characterized by low signal intensity on both T2-WI and DWI and an enhancing area of $\leq$3 mm at the original tumor site.

PI-FAB 3: Identified by early focal enhancement >3 mm within the ablated zone or edge, or an increase in size of a PI-FAB 2 focus. High signal intensity on DWI focal enhancement of any size, and low signal intensity on T2-WI and the ADC map also indicate a high suspicion of residual or recurrent disease.

PI-FAB 1 typically suggests continued monitoring, PI-FAB 2 may lead to assessing PSA dynamics and possibly a biopsy, especially if PSA is rising, and for PI-FAB 3, a biopsy is generally recommended.

2.3. Statistical analysis

Gwet's agreement coefficient 1 (AC1) with 95 % confidence intervals (95 %-CI) [12,13] was calculated to evaluate inter-reader agreement, as it is less influenced by marginal probability and prevalence than Cohen's Kappa [14]. Interpretation of agreement levels was conducted according to the classification system by Landis and Koch [15].

The histopathologic results of the subsequent prostate biopsies after follow-up mpMRI at 6, 12, and 36 months post-HIFU therapy served as the standard-of-reverence to assess the diagnostic performance of the PI-FAB ratings. For the statistical analysis, a PI-FAB score of 1 indicated an absence of tumor evidence and was categorized as "test negative," while a PI-FAB score of 2 or 3 signified potential tumor presence and was categorized as "test positive." Histopathologic biopsy results showing a Gleason score of $\geq$3 + 3 (ISUP/WHO grade group 1) were considered as positive, consequently confirming the presence of prostate cancer or "outcome positive". Conversely, a Gleason score of <3 + 3 (ISUP/WHO grade group 1) indicated a negative biopsy result or "outcome negative." Accordingly, measures such as sensitivity (SENS), specificity (SPEC), positive predictive value (PPV), and negative predictive value (NPV) were computed.

The level of significance was set to 5 %. The software R (version 4.3.2) was used for all statistical analysis [16].

3. Results

From May 2014 to April 2019 initially 99 patients who had undergone HIFU treatment and had baseline mpMRIs available prior to their treatment were identified for the purpose of our study. However, 26 patients were excluded due to incomplete follow-up with MRI or missing

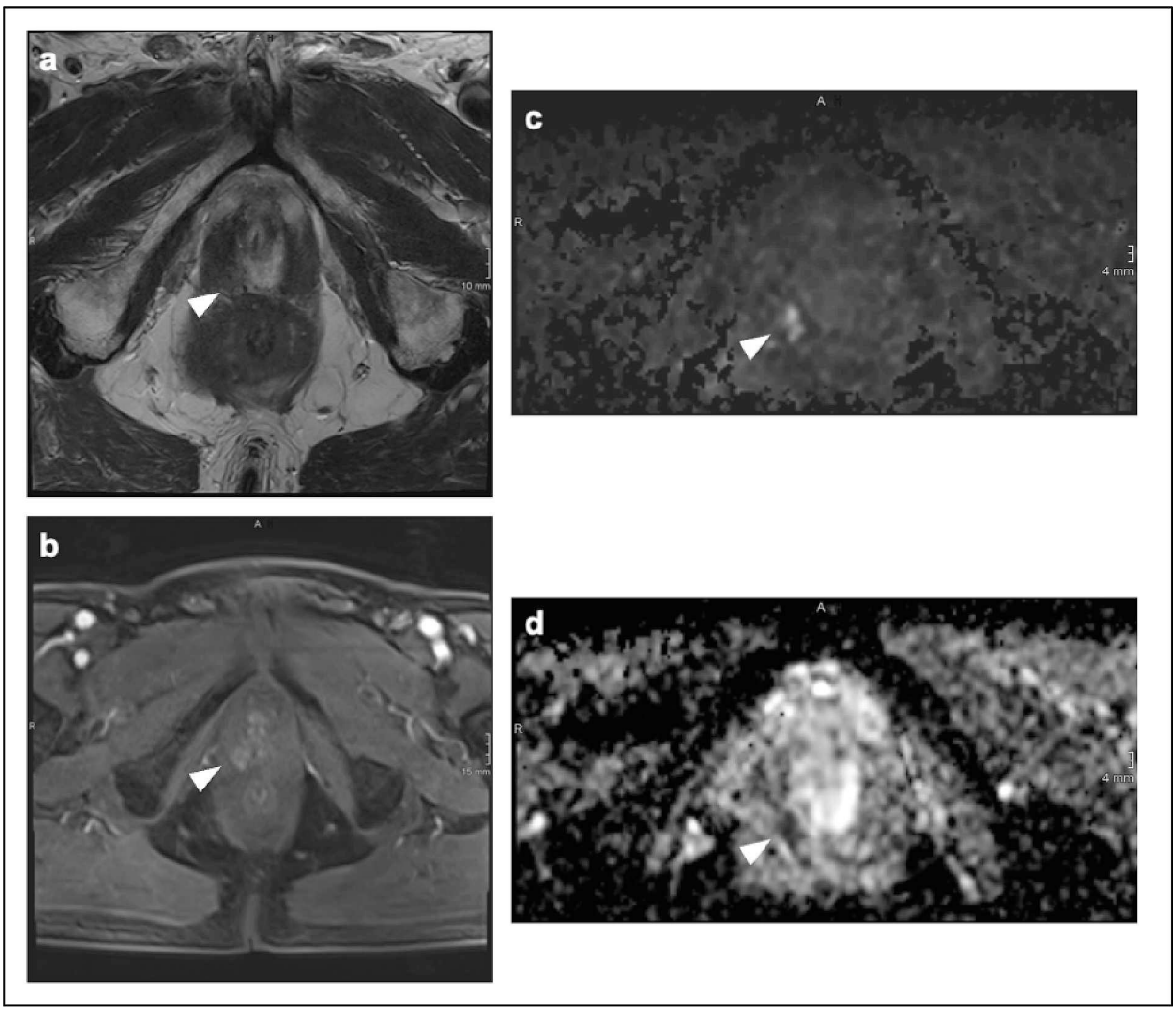

Fig. 2. Multiparametric MRI 36 months after focal HIFU therapy of prostate cancer in the right apical posteromedial and posterolateral peripheral zone. Suspicious lesion with low signal intensity on T2w-imaging (arrowhead in a), diffusion restriction (arrowheads in c/d) and focal enhancement (arrowhead in b) at the lower edge of the ablation zone in the apical right posteromedial peripheral zone, classified as PI-FAB 3. Subsequent biopsy in combination with histopathology revealed a local recurrence of a clinically significant prostate cancer (Gleason score 4 + 4, ISUP/WHO grade group 4). PSA dynamics were as follows (in ng/ml): 5.50 (pre-HIFU); 0.96 (6 months post-HIFU); 1.23 (12 months post-HIFU); 4.60 (36 months post-HIFU).

subsequent biopsy at 6 months post-HIFU. The final study cohort therefore consisted of 73 men.

Median age was 66 years (IQR 61–70 years) and median PSA-value was 6.0 ng/ml (IQR 4.5 – 7.6 ng/ml). Distribution of ISUP/WHO grades of Gleason scores prior to HIFU treatment was as follows: grade group 1 in 4/73 patients (5.5 %), grade group 2 in 50/73 patients (68.5 %) and grade group 3 in 19/73 patients (26.0 %). Patient characteristics are summarized in Table 1.

At 6 months post-HIFU, 73 men (100 %) underwent follow-up mpMRI with subsequent biopsy, of which 7/73 (9.6 %) showed an in-field residual or recurrent PCa, with 4/73 cases (5.5 %) of ISUP/WHO grade group 2 and 3/73 cases (4.1 %) of ISUP/WHO grade group 4, consequently all meeting the criteria of csPCa (ISUP/WHO grade group $\geq$2).

At 12 months post-HIFU, follow-up MRI with subsequent biopsy was available for 51/73 men (69.9 %). 7/51 (13.7 %) showed an in-field residual or recurrent disease, with 4/51 cases (7.8 %) of ISUP/WHO grade group 2, 2/51 cases (3.9 %) of ISUP/WHO grade group 3, and 1/51 case (2.0 %) of ISUP/WHO grade group 4. Consequently, all cases of in-field residual or recurrent disease were classified as csPCa.

At 36 months post-HIFU, 41/73 men (56.2 %) underwent follow-up mpMRI with subsequent biopsy. 2/41 (4.9 %) showed an in-field recurrent disease, with 1/41 case (2.4 %) of ISUP/WHO grade group 3 and 1/41 case (2.4 %) of ISUP/WHO grade group 4. Consequently, both met the criteria of csPCa.

Table 2 presents the PSA levels, ISUP/WHO grades, PI-FAB scores from both readers, and the applied managment strategies for cases involving in-field residual or recurrent prostate cancer.

3.1. *Inter-reader agreement for the PI-FAB score*

Inter-reader agreement for the PI-FAB scores was almost perfect on the follow-up MRIs 6 months and 12 months after HIFU treatment (6 months post-HIFU: AC1 0.90, 95 %-CI 0.82–0.97, 12 months post-HIFU: AC1 0.95, 95 %-CI 0.90–1.0) and substantial on the follow-up MRIs 36 months post-HIFU (AC1 0.80, 95 %-CI 0.64–0.97).

Of note, the more experienced reader utilized the PI-FAB 2 score only once in the evaluation of the follow-up MRIs at 6 and 12 months post-HIFU treatment, while the less experienced reader did not assign a PI-FAB 2 score in any of his/her ratings across all assessments. Fig. 1 and Fig. 2 present two different examples of a residual/recurrent in-field PCa on mpMRIs 6 months and 36 months post-HIFU. In addition, Fig. 3 and

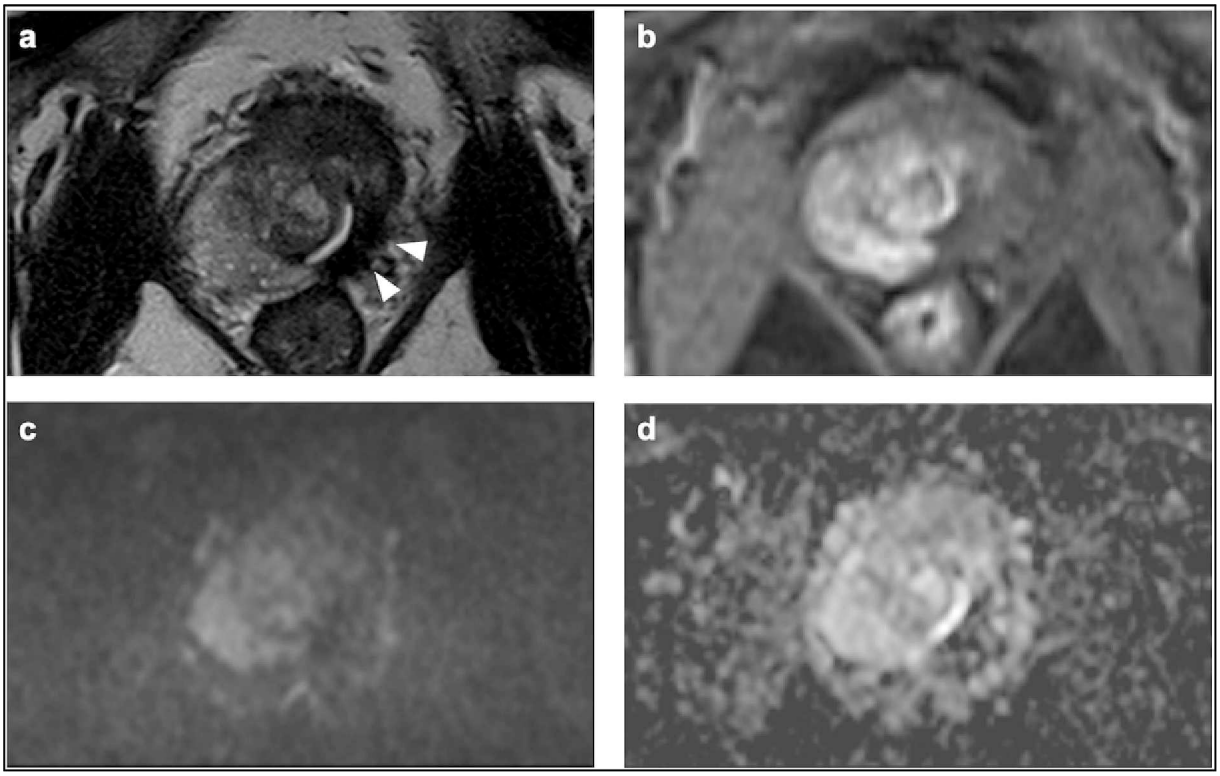

Fig. 3. Multiparametric MRI 36 months after focal HIFU treatment of prostate cancer in the left midglandular prostate. T2w-hypointense scarring and prostate atrophy (arrowheads in a) within the ablation zone, no suspicious lesion on DCE (b) or DWI (c/d). Consequently, there was no evidence for a local recurrence of prostate cancer on imaging (PI-FAB 1 score by both readers), which was confirmed by subsequent biopsy with a negative histopathology. PSA dynamics were as follows (in ng/ml): 3.38 (pre-HIFU); 2.20 (6 months post-HIFU); 2.72 (12 months post-HIFU); 1.95 (36 months post-HIFU).

Fig. 4 depict examples of PI-FAB 1 and PI-FAB 2 scores.

3.2. Diagnostic performance of the PI-FAB scores

The diagnostic performance of the PI-FAB score, assessed in relation to the histopathologic results of saturation and targeted biopsies, revealed distinct patterns and disparities between the more and less experienced reader (see Table 3).

For the more experienced reader, the sensitivity of the PI-FAB score for detecting residual or recurrent PCa at 6, 12, and 36 months after HIFU treatment was 43 %, 43 % and 100 %, respectively. Specificity remained high, with values of 97 %, 98 %, and 90 % for the respective time points. The PPV showed variability (60 %, 75 %, and 33 %), whereas the NPV was consistently high with values of 94 %, 91 % and 100 % at the respective time points.

Conversely, the less experienced reader exhibited lower sensitivity values at the respective time points, recording 14 %, 14 %, and 50 %, but specificity remained relatively high (95 %, 98 %, and 87 %). While the PPV for this reader, was notably lower, (25 %, 50 %, and 17 %), the NPV was comparatively high (but still lower than that of the more experienced reader) with values of 91 %, 88 %, and 97 % at the corresponding time points of follow-up.

4. Discussion

As focal ablation has become a viable treatment option for prostate cancer, it is essential to establish a consistent approach for post-treatment monitoring. Our retrospective study explored the recently developed PI-FAB score [10], applied to follow-up mpMRIs in a clinical cohort treated with HIFU therapy. Inter-reader agreement for the PI-FAB scores was substantial to almost perfect according to Gwet's AC 1 (AC1 0.80–0.95). Notably, the PI-FAB 2 score was not used by the less experienced reader at all and only twice by the experienced reader in the whole assessment of follow-up MRIs after HIFU therapy. This could be explained by the specific criteria of the PI-FAB 2 score which require a low signal intensity on both T2-WI and DWI and an enhancing area of $\leq$3 mm at the original tumor site. However, it is important to recognize that especially small lesions $\leq$3 mm exhibiting these features might pose a challenge in differentiation from common post-ablative changes due to scarring and could explain the limited use of the PI-FAB 2 score in our study.

Our study demonstrated relatively low sensitivities (Reader 1/Reader 2) of 43 %/14 %, contrasted with high specificities (Reader 1/Reader 2) of 97 %/95 % at 6 months post-HIFU. Similarly, at 12 months post-HIFU, sensitivities were 43 %/14 %, while specificities were notably higher at 98 %/98 %. Due to the low number of in-field recurrent PCa (2 cases) 36 months post-HIFU the sensitivity of 100 %/50 % and specificity of 90 %/87 % must be interpreted with caution. Overall, the relatively low sensitivities and PPVs of the two readers might in part be attributed to the low number of cases with in-field residual or recurrent prostate cancer. The more experienced reader demonstrated superior sensitivity, specificity, PPV, and NPV at most time points, indicating the potential impact of experience on their diagnostic accuracy.

A comprehensive *meta*-analysis by Ahn et al. [17] explored the diagnostic performance of MRI post-HIFU. The pooled sensitivity for general MRI-based prediction of recurrent PCa was found to be 81 % (95 % CI 72 %–90 %), while the specificity was 91 % (95 % CI 86 %–96 %). However, larger studies that included more than 50 patients documented inferior diagnostic performance with a sensitivity of 68 % (95 % CI 50 %–91 %) and specificity of 75 % (95 % CI 61 %–92 %). It is well known that PCa of low grade and small size may be missed on mpMRI [18,19]. In the post-procedural setting after HIFU treatment additional challenges may arise from asymmetry due to residual prostate

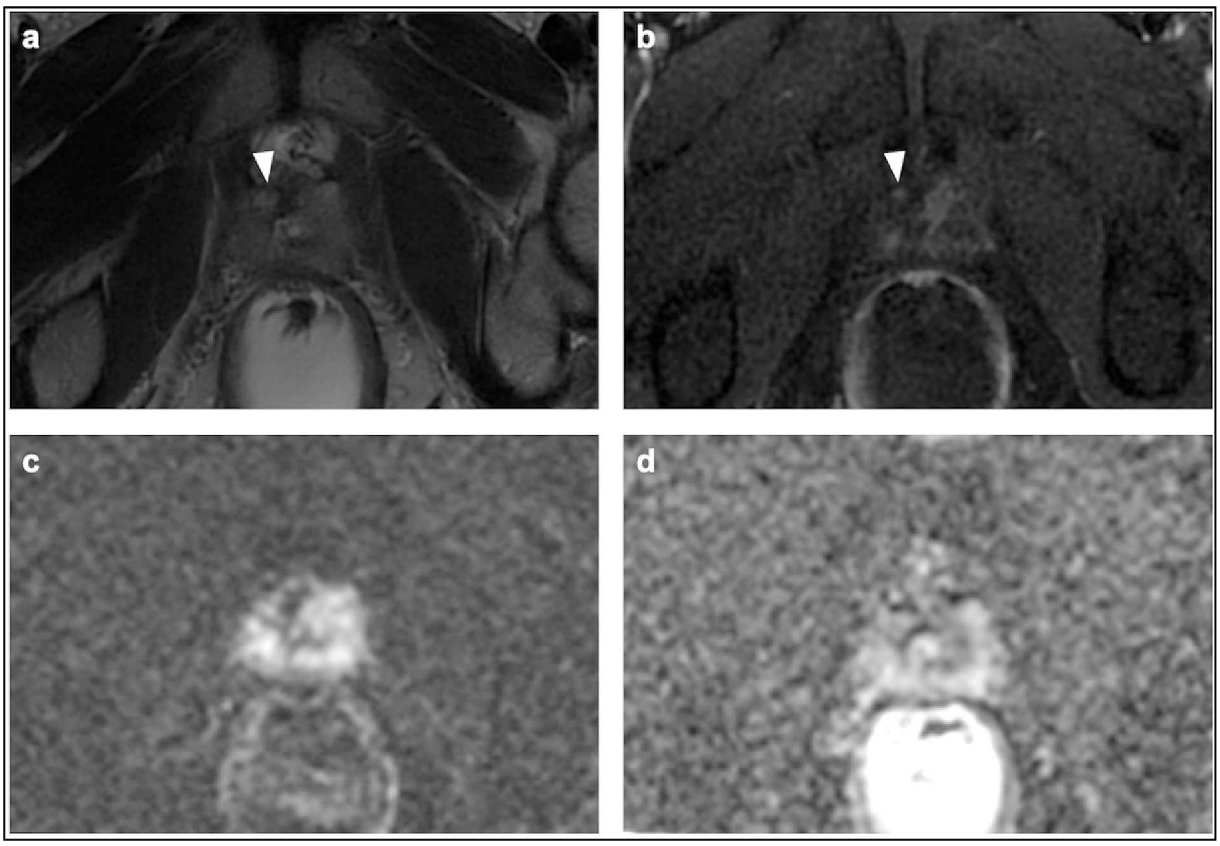

Fig. 4. Multiparametric MRI 12 months after focal HIFU treatment of prostate cancer in the right midglandular prostate. Small suspicious lesion with low signal intensity on T2w-imaging and focal enhancement (arrowheads in a and b) without definitive hyperintense correlate on DWI at the anterior border of the ablation zone in the apical right anterior peripheral zone, classified as PI-FAB 2 by Reader 1 and PI-FAB 1 by Reader 2. Subsequent biopsy in combination with histopathology revealed a local recurrence of a clinically significant prostate cancer (Gleason score 3 + 4, ISUP/WHO grade group 2). PSA dynamics were as follows (in ng/ml): 8.10 (pre-HIFU); 1.29 (3 months post-HIFU); 0.87 (6 months post-HIFU); 2.86 (12 months post-HIFU).

Table 3
Statistical parameters of diagnostic performance of the PI-FAB score for the retrospective evaluation of residual or recurrent prostate cancer at various follow-up intervals after high-intensity focused ultrasound (HIFU) therapy for prostate cancer. Results of the follow-up multiparametric MRIs 6, 12 and 36 months post-HIFU were all compared to the histopathologic results of saturation and targeted prostate biopsy as standard-of-reference.

Diagnostic performance of the PI-FAB / Time point of follow-up/ Reader	SENS (%, 95 %-CI)	SPEC (%, 95 %-CI)	PPV (%, 95 %-CI)	NPV (%, 95 %-CI)
6 m post-HIFU (n = 73)				
Reader 1	43 (10–82)	97 (89–100)	60 (15–95)	94 (86–98)
Reader 2	14 (0–58)	95 (87–99)	25 (1–81)	91 (82–97)
12 m post-HIFU (n = 51)				
Reader 1	43 (10–82)	98 (88–100)	75 (19–99)	91 (80–98)
Reader 2	14 (0–58)	98 (89–100)	50 (1–99)	88 (75–95)
36 m post-HIFU (n = 41)				
Reader 1	100 (16–100)	90 (76–97)	33 (4–78)	100 (90–100)
Reader 2	50 (1–99)	87 (73–96)	17 (0–64)	97 (85–100)

Reader 1: experienced reader. Reader 2: less experienced reader.SENS: sensitivity, SPEC: specificity, PPV: positive predictive value, NPV: negative predictive value, 95%-CI: 95% confidence interval, m: months.

parenchyma, and its implications for the distinction between in-field cancer recurrence and new out-of-field tumors [17].

mpMRI of the prostate is widely recognized as a reliable tool for excluding csPCa [20,21]. Accordingly, in the setting after HIFU treatment our study emphasizes the high efficacy of MRI in ruling out in-field residual/recurrent csPCa with NPVs (Reader 1/Reader 2) of 94 %/91 %, 91 %/88 % and 100 %/97 % at 6 months, 12 months, and 36 months post-HIFU, respectively.

A recent trial conducted by Gelikman et al. [22] assessed the PI-FAB score within a cohort of 38 patient subjected to various focal therapy modalities, revealing a high sensitivity of 93 % alongside variability in specificity, PPVs, NPVs and overall accuracy. In comparison to our study these differences may be partly due to the small size and diversity of the cohorts studied. Despite these discrepancies, both our studies underscore the utility of the PI-FAB score in monitoring post-treatment prostate cancer but also highlight an ongoing need for the score's refinement and further validation. As already stated by Kaufmann et al. [20] combining PSA kinetics with imaging results might enhance their utility in monitoring patients after focal therapy. Similarly, when employing the PI-FAB score, Giganti et al. [10] recommends to take into account the MRI results alongside the comprehensive clinical context, encompassing PSA kinetics, the initial risk stratification of PCa, and patient-specific factors, including eligibility for additional focal or radical treatment and patient preferences.

This study has some limitations. The retrospective design, relatively small cohort size and limited number of in-field residual or recurrent PCa could potentially restrict the generalizability of the research findings. Some patients were excluded from the study analysis at certain timepoints due to incomplete follow-up with MRI in combination with

subsequent biopsy. This could affect the integrity of the data and potentially introduce bias. Another important limitation to consider might be the image quality of the study MRIs which were acquired between April 2014 to April 2019. As with all imaging examinations, it is well known that the diagnostic accuracy of MRI is also greatly dependent on the quality of the images [23–27]. These limitations should be considered when interpreting and applying the study's findings, and future research may address some of these challenges to enhance the understanding of post-HIFU monitoring using the PI-FAB score.

5. Conclusion

Our findings suggest that the PI-FAB score can be consistently applied in patients undergoing post-HIFU monitoring by both experienced and less experienced readers, as indicated by substantial to almost perfect inter-reader agreement. However, the potential impact of experience on diagnostic performance must be considered. Furthermore, the study underscores the potential of mpMRI in conjunction with the PI-FAB score as a promising and effective tool especially for ruling out in-field residual or recurrent prostate cancer following HIFU treatment.

In conclusion, the combination of mpMRI and the PI-FAB score may contribute to improved patient care as a valuable non-invasive monitoring approach after focal ablative therapy of the prostate.

CRediT authorship contribution statement

Antonia M. Pausch: Data curation, Conceptualization, Formal analysis, Investigation, Methodology, Resources, Software, Writing – original draft. **Clara Elsner:** Data curation, Investigation, Resources, Writing – review & editing. **Niels J. Rupp:** Resources, Writing – review & editing. **Daniel Eberli:** Resources, Writing – review & editing. **Andreas M. Hötker:** Conceptualization, Formal analysis, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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