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Parameters predicting Recurrence after

Focal Therapy for Prostate Cancer:

Insights from a Multicenter Surveillance Database

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Abstract

Introduction: Focal therapy (FT) represents a minimally invasive option for selected patients with localized prostate cancer (PCa), aiming to achieve oncological control while preserving functional outcomes. Despite its increasing adoption, long-term efficacy data remain limited, and predictors of recurrence are not well defined.

Methods: We conducted a retrospective multicenter cohort study of 209 men with histologically confirmed unifocal or oligo-focal (≤3 lesions) PCa treated with FT (high-intensity focused ultrasound [HIFU], vascular-targeted photodynamic therapy [VTP], cryotherapy, or transurethral ultrasound ablation [TULSA]) between 2019 and 2024 at three German centers. Clinical, histopathological, treatment-related, and multiparametric MRI (mpMRI) parameters were prospectively collected in a REDCap-based registry. Recurrence-free survival (RFS) and progression-free survival (PFS) were analyzed using Kaplan–Meier estimates, and Cox regression was applied to identify independent predictors.

Results: Median patient age was 66 years, and median PSA was 6.4 ng/mL. ISUP grade distribution was 58% grade 1, 29% grade 2, and 13% grade ≥3. Treatment modalities comprised HIFU (43%), VTP (35%), cryotherapy (12%), and TULSA (10%). After a median follow-up of 1.73 years, 40% of patients developed recurrence and 15% showed histologic progression. RFS varied by treatment modality (HIFU: 2.26 years; VTP: 1.73 years; cryotherapy: 0.75 years; TULSA: not reached; $p = 0.001$). Median PFS was 4.7 years. Suspicious baseline mpMRI (PI-RADS 4–5) was associated with shorter RFS. Suspicious follow-up mpMRI strongly predicted both recurrence (RFS 1.1 vs. 2.96 years, $p < 0.001$) and progression (PFS 1.8 vs. 4.7 years, $p = 0.004$). In multivariate analysis, suspicious follow-up mpMRI was the only independent predictor of recurrence (HR 2.07, 95% CI 1.24–3.45, $p = 0.005$).

Conclusions: In this multicenter registry analysis, recurrence after FT was frequent, affecting 40% of patients within two years. mpMRI findings before and especially after treatment emerged as the strongest predictors of oncological failure, underscoring the central role of standardized imaging in patient selection and surveillance. Prospective studies with longer follow-up and centralized radiologic review are needed to refine FT protocols and optimize patient outcomes.

Introduction

Focal therapy (FT) has emerged as a promising therapeutic approach for patients with localized, unifocal or limited multifocal (≤3 lesions), low- and intermediate-risk prostate cancer (PCa). The primary aim of FT is to achieve effective oncological control by selectively targeting malignant tissue while preserving surrounding anatomical structures, thus minimizing functional adverse effects such as urinary incontinence and erectile dysfunction. FT is currently endorsed by national and international guidelines as an established treatment option for carefully selected patients within these risk categories.[8, 10]. However, since active surveillance is regarded as preferred option in low- and intermediate-risk PCa, indication for FT in more aggressive PCa has to be proven. Especially in these cases, patient's selection is getting more and more important for cancer control.

Several FT modalities have been investigated, including high-intensity focused ultrasound (HIFU), cryotherapy, transurethral ultrasound ablation (TULSA), and vascular-targeted photodynamic therapy (VTP), with HIFU currently representing the most widely adopted approach. Despite increasing clinical implementation, FT remains subject to ongoing debate, primarily due to limited long-term oncological outcome data and the lack of standardized protocols for patient selection, treatment planning, and follow-up. A critical challenge is the accurate identification of patients who will benefit most from FT, balancing effective cancer control against the risk of recurrence or disease progression. Indeed, reported recurrence rates vary significantly, ranging from 20% to 50% within five years post-treatment, depending on the modality employed and the follow-up criteria applied.[9].

Multiparametric magnetic resonance imaging (mpMRI) plays a central role throughout the diagnostic and therapeutic pathway in FT. It provides detailed anatomical and functional information essential for localizing suspicious lesions, guiding targeted biopsies, and monitoring the prostate during post-treatment surveillance. Nonetheless, robust real-world data assessing the predictive value of imaging parameters and other clinical factors for recurrence and progression remain limited.

In this multicenter study, we aimed to analyze recurrence and progression rates following FT based on data from a national follow-up registry, to evaluate the impact of clinical, histopathological, and imaging-derived parameters on oncological outcomes, and to identify reliable predictors of treatment failure. Ultimately, our goal was to refine patient selection criteria and optimize follow-up protocols for patients undergoing FT.

Patients and Methods

This retrospective, multicenter cohort study analyzed data collected from three academic institutions in Germany (Dresden, Hannover, and Magdeburg) between 2019 and 2024. Data collection was facilitated by a web-based registry (REDCap®) specifically developed for the follow-up of patients undergoing focal therapy (FT) for localized prostate cancer (PCa). Ethical approval was granted by each participating institution. The study was approved by the Institutional Review Board of the university hospital Dresden (Vote: BO-EK-259062020). During the transfer into the REDCap® database, only anonymized datasets were imported, without any names, dates of birth, addresses, or comparable identifiers. The analysis included only clinical and diagnostic parameters (e.g., PSA levels, prostate volumes, PI-RADS scores, and histopathological findings). Therefore, additional individual informed consent from the patients was not required.

Eligible patients included those diagnosed with histologically confirmed unifocal or oligo-focal (≤3 lesions) PCa who underwent FT employing HIFU, cryotherapy, TULSA, or VTP. Inclusion criteria required multiparametric MRI in combination with MRI–ultrasound fusion biopsy (targeted and systematic) or a transperineal template biopsy enabling three-dimensional anatomical assignment of findings. At least one Follow-up examination has to be available between 6 and 18 months after focal therapy and had to correspond to the baseline inclusion criteria. Only patients with comprehensive baseline, treatment, and follow-up datasets were included, resulting in a final cohort of 209 patients. All data were prospectively recorded in a REDCap®-based electronic database hosted at the Clinical Trial Coordination Center at the University Hospital Dresden.

Collected variables encompassed pre-treatment data (age, prostate-specific antigen [PSA] levels, PSA density, digital rectal examination findings, prostate volume, multiparametric magnetic resonance imaging [mpMRI] parameters—lesions were classified as suspicious for clinically significant PCa only if scored PI-RADS 4 or 5—and histopathological biopsy results including ISUP grade, Gleason score, and tumor core location). Treatment-related parameters comprised FT modality, ablation zone and volume, as well as treatment duration.

Follow-up data consisted of PSA measurements, follow-up mpMRI findings, repeat biopsies, and clinically relevant events such as biochemical recurrence, radiologic or histologic tumor progression, metastasis, or death. Any salvage therapies and their outcomes were also systematically documented. In follow-up MRI, since PI-RADS classification was not applicable, we distinguished in tumor-suspicious vs. not suspicious. All interpreting radiologists across participating sites were highly experienced. All mpMRI sequences were considered for assessment. Because PI-RADS classification was not applicable in follow-up MRI, findings were categorized in a binary manner as tumor-suspicious versus not suspicious. In analogy to the PI-FAB score, particular emphasis was placed on diffusion-weighted imaging and the contrast-enhanced phase.

Biochemical recurrence was defined by a rise in PSA levels confirmed by radiologic or histologic evidence of recurrent disease. Tumor progression was defined histologically by an upgrade in ISUP grade compared to baseline. Recurrence within the original ablation zone was classified as infield recurrence, whereas recurrence outside this zone was designated as outfield recurrence. Recurrence-free survival (RFS) and progression-free survival (PFS) were calculated from the date of FT until the occurrence of the respective event or until last follow-up.

Descriptive statistical methods were utilized to characterize baseline demographics and clinical features. Kaplan–Meier analyses were employed to estimate RFS and PFS. Univariate and multivariate Cox proportional hazards regression models were used to identify independent predictors of recurrence and progression. Variables with a significance level of $p < 0.05$ in univariate analyses were subsequently included in multivariate models. A two-sided p-value of < 0.05 was defined as statistically significant. Statistical analyses were performed using SPSS (version 29.0) and R (version 4.2).

Results

Patient Characteristics. As shown in Table1, a total of 270 patients were enrolled in the registry; 209 patients had complete datasets and were included in the final analysis. The median age was 66 years (IQR 59–71), the median PSA level was 6.40 ng/mL (IQR 4.94–8.31), and the median PSA density was 0.17 ng/mL^2 (IQR 0.12–0.24). At diagnosis, 58% had ISUP grade 1, 29% grade 2, and 13% grade ≥3 PCa. A diagnostic mpMRI was available in 50% of patients, with 79% of those showing PI-RADS 4 or 5 lesions.

Table 1: epidemiological data

Treatment Distribution. Among the 209 patients 90 (43%) underwent HIFU, 73 (35%) VTP,26 (12%) cryotherapy and 22 (10%) TULSA. In 18% of cases (n = 37), bilateral ablation was performed. Figure 1 shows the patient inclusion and therapy modalities.

Figure 1. **CONSORT** (Consolidated Standards of Reporting Trials)- *diagram of patient inclusion and therapy modalities.*

Oncologic Outcomes. After a median follow-up of 1.73 years (95% CI 1.18–2.28), 84 patients (40%) experienced a recurrence, and 32 of them (38%) showed histologic progression to a higher ISUP grade (in total 15%). All patients underwent at least one follow-up evaluation. The first assessment was performed after a median of 12 months. Patients with mpMRI received a consecutive MRI–ultrasound fusion control biopsy, whereas patients without mpMRI underwent a template biopsy. Additional mpMRI and/or biopsies were performed only when clinically indicated (e.g., PSA increase). Among recurrent cases 24% had outfield recurrence, 20% infield recurrence, and 18% had both infield and outfield disease (in 32 patients the localization of the PCa recurrence was not documented).

The overall RFS varied significantly by FT modality: Cryotherapy: 0.75 years; TULSA: median not reached; VTP: 1.73 years (95% CI 1.07–2.39); HIFU: 2.26 years (95% CI 1.66–2.87) (p = 0.001).

The median PFS across all modalities was 4.7 years (95% CI 1.395–7.981).

Imaging Predictors. Patients with initial tumor-suspicious mpMRI showed significantly shorter median RFS compared to those with no suspicious MRI. 1.1 years (95% CI 1.014–1.20) vs. not reached (NR); p = 0.041. No significant difference in PFS was observed between these groups. Figures 2 and 3 show recurrence-free and radiological progression-free survival depending on the baseline MRI.

Figure 2. *RFS based on findings on initial MRI*

Figure 3. *PFS based on findings on initial MRI*

Patients with tumor-suspicious MRI during follow-up had significantly higher recurrence rates (67% vs. 34%) and shorter RFS: 1.1 years (95% CI 0.81–1.4) vs. 2.96 years (95% CI 1.34–4.59), p < 0.001. Also for tumor progression, patients with tumor-suspicious MRI during follow-up had significantly higher recurrence rates (29% vs. 11%) and shorter PFS: 1.8 years (95% CI 1.19–2.4) vs. 4.7 years (95% CI 0.00 –9,67), p =0.004. Figures 4 and 5 show recurrence-free and radiological progression-free survival depending on the Follow-up MRI.

Figure 4. *RFS according to follow-up MRI findings.*

Figure 5. *PFS according to follow-up MRI findings.*

Multivariate Analysis. Multivariate Cox regression analysis identified only suspicious follow-up mpMRI (HR 2.07, 95%-CI 1.241-3.454; p = 0.005) as independent predictor of recurrence. No independent predictors for tumor progression could be identified.

Discussion

This multicenter analysis provides real-world evidence regarding oncological outcomes and predictive factors following focal therapy (FT) for localized prostate cancer (PCa) within a German patient cohort. With a median follow-up duration of 1.73 years, the biochemical recurrence rate was 40%, and histologic progression occurred in 15% of patients. mpMRI findings obtained both before and after treatment were notably identified as the strongest independent predictors of recurrence, highlighting the pivotal role of advanced imaging in patient selection and post-treatment monitoring strategies. In cross table 2, the results of the MRI before and after therapy are presented. Our observed recurrence rates align closely with previously published data, reporting recurrence in approximately 20% to 50% of cases, depending on the focal therapy modality employed, duration of follow-up, and specific criteria used to define recurrence.[9]. Among the examined FT modalities, some studies have indicated higher recurrence rates and shorter recurrence-free survival associated with cryotherapy compared to alternative approaches, whereas other reports suggest comparable oncological outcomes across techniques.[9]. Notably, HIFU has shown favorable results in several series[7]. However, current evidence remains heterogeneous and insufficient to draw definitive conclusions regarding the superiority of any one FT modality over another.

A notable contribution of the present study is the identification of pre- and post-interventional MRI findings as independent predictors of recurrence. Specifically, patients presenting with suspicious lesions (PI-RADS 4/5) on baseline mpMRI demonstrated significantly shorter RFS compared to those without such findings. In the present cohort, due to the multicenter design of the study, information is lacking as to whether the histologically confirmed recurrences represent in-field or out-of-field recurrences. If a high number of in-field recurrences were present, it could indicate that imaging-positive tumors are more resistant to ablative energy, or that the safety margin around the visible lesion was consistently too narrow, allowing tumor cells present in this non-visible peripheral zone to survive.

Conversely, it is also conceivable that smaller, non-visible foci adjacent to a larger visible tumor may be more easily missed during treatment planning. This could account for a higher rate of out-of-field recurrences.

Similarly, suspicious lesions identified on follow-up MRI showed a strong correlation with recurrence. A visible lesion can be targeted more reliably during fusion biopsy, whereas non-visible lesions remain incidental findings. In patients undergoing active surveillance, the so-called PRECISE score can be applied It is a tool designed to standardize reporting and to objectify potential tumor progression. By using this score, aside from the mandatory re-biopsy at 6–12 months, approximately two-thirds of the biopsies previously considered standard can be avoided. Unfortunately, the PRECISE score is not applicable to treated glands[1]. Therefore, the PI-FAB score in mpMRI after FT and the PI-RR score after radiotherapy were developed.

These results underscore the pivotal dual role of mpMRI in risk stratification and the early detection of treatment failure. Nevertheless, only 50% of patients underwent pre-treatment mpMRI, representing a critical limitation likely attributable to historical differences in imaging availability or inconsistent adherence to diagnostic protocols among participating centers.

Moreover, post-treatment MRI interpretation following FT remains challenging and prone to various diagnostic pitfalls, including treatment-related changes that may closely resemble residual or recurrent disease[5]. In 2023, Giganti and colleagues proposed a standardized scoring system for the interpretation of post-treatment MRI in patients undergoing focal therapy for prostate cancer. This consensus-based framework, known as PI-FAB (Prostate Imaging – Focal Ablation), was developed to facilitate consistent evaluation of ablation effects and potential residual or recurrent disease, by comparing post-treatment imaging findings to baseline MRI. Structurally similar to PI-RADS, the PI-FAB system comprises five categories reflecting the likelihood of clinically significant residual cancer[3].

Petrocelli et al. recently developed an MRI-based score, which was evaluated in a cohort of 142 patients. It enabled greater accuracy in predicting recurrence following focal therapy[6].

However, at the time of data collection for our retrospective study, such scoring systems were not yet available. Since the retrospective character of our study, we did not have the opportunity to perform a second reading by prostate MRI experts, so we could not provide a re-evaluation by PI-FAB or Petrocelli score.

Interestingly, in our cohort, PSA response was not identified as a predictor of recurrence in multivariate analysis. Conversely, the predictive value of a PSA rise for recurrence increases with the extent of tissue ablation—the more comprehensive the treatment, the more reliable the PSA kinetics become as a surrogate marker for oncological failure. We hypothesize that this may be due to the dependence of PSA dynamics on the volume of prostate tissue treated. This is supported by findings from previous studies: in the HIFI trial, where a subtotal ablation of the prostate was performed using HIFU, a marked PSA reduction was observed[7]; in contrast, the HEMI study, which applied hemiablation, showed a moderate PSA response[2], while in the study by Kaufmann employing small and targeted ablation zones, the PSA effect was minimal[4].

In our cohort, the majority of patients underwent HIFU with minimally extensive focal therapy. Among cryotherapy and TULSA patients, treatment volumes were heterogeneous, while VTP patients predominantly received hemiablation. This variability likely limits the utility of PSA dynamics as a universal indicator of treatment success or failure across focal therapy modalities.

The study also revealed a considerable proportion of outfield recurrences (24%) and mixed infield/outfield cases (18%), supporting the hypothesis that undetected multifocal disease remains a limitation of FT, particularly when mpMRI is absent or inconclusive. This reinforces the need for accurate mapping biopsies and comprehensive imaging before initiating FT.

From a clinical standpoint, our findings advocate for standardized imaging protocols both before and after FT. The establishment of a national surveillance registry proved feasible and valuable for tracking outcomes and complications across multiple centers. Such infrastructure is essential for continuous quality control and evidence generation in evolving treatment strategies like FT.

Limitations

This study is limited by its retrospective design, non-standardized imaging interpretation (no central radiologic review), and the lack of application of the recently proposed Failure-scoring systems for post-treatment MRI assessment.

A major limitation of our current analysis is that no second reading or central radiological review was performed. As a result, all MRI assessments were based solely on the subjective interpretation of a single radiologist at the University Hospital in Dresden. We consider the use of standardized scoring systems such as PI-FAB, together with independent radiological review, to be mandatory components of future prospective studies in this field.

Furthermore, significant gaps exist in the documentation of functional outcomes and health-related quality of life. These limitations are primarily due to the retrospective nature of the study and the fact that the four participating centers applied different focal therapy modalities and heterogeneous follow-up protocols, which complicates standardized outcome collection and comparison. Future prospective studies should address these limitations by implementing uniform follow-up schemes and validated instruments for assessing functional and quality-of-life parameters.

Additionally, follow-up duration may be insufficient to capture long-term oncological endpoints, including metastasis or prostate cancer-specific mortality. Furthermore, therapy selection was not randomized and may have been influenced by center-specific preferences or patient comorbidities.

Conclusion and Future Directions

Focal therapy offers a tissue-preserving option for selected patients with localized PCa. Our findings confirm that mpMRI is a critical tool for predicting recurrence and should be integrated into every step of the FT pathway—from patient selection to follow-up. Future studies should aim for prospective design, centralized imaging review, and longer follow-up to validate these findings and refine selection criteria. The continued use and expansion of structured surveillance registries will be essential for improving outcomes and ensuring safe implementation of FT in daily practice.

Statement of Ethics

The study was approved by the Institutional Review Board of the university hospital Dresden (Vote: BO-EK-259062020). Written informed consent was obtained from participants to participate in the study.

Conflict of Interest Statement

Martin Schostak is the Managing Director and Medical Director of LOGICURO GmbH, Potsdam, Germany, and serves as a consultant for EDAP-TMS.

Martin Schostak, Stefan Machtens, Heinz-Peter Schlemmer, and Angelika Borkowetz are members of the *Arbeitskreis für Fokale und Mikrotherapie* of the German Society of Urology.

All other authors declare no conflicts of interest related to this work.

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Author Contribution Statement

Emma Peklo performed the data entry and database management.

Martin Schostak, Angelika Borkowetz, Stefan Machtens and Inga Peters contributed patient data to the multicenter registry.

Angelika Borkowetz conducted the statistical analysis.

Martin Schostak and Angelika Borkowetz wrote the manuscript.

Heinz-Peter Schlemmer and Christian Thomas critically revised the study design and the paper for important intellectual content.

All authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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Figure Legends

Figure 1: CONSORT Diagramm (Consolidated Standards of Reporting Trials

The CONSORT diagram illustrates which focal therapy modality was performed in each of the 270 patients. After applying key inclusion and exclusion criteria, the final analysis included 90 patients treated with HIFU, 26 with cryotherapy, 22 with TULSA, and 80 with VTP.

Figure 2: Recurrence-free Survival depending on initial MRI

The Kaplan–Meier analysis shows a significant difference in recurrence-free survival between patients with initially suspicious versus non-suspicious MRI findings.

Figure 3: Progression-free Survival, depending on initial MRI

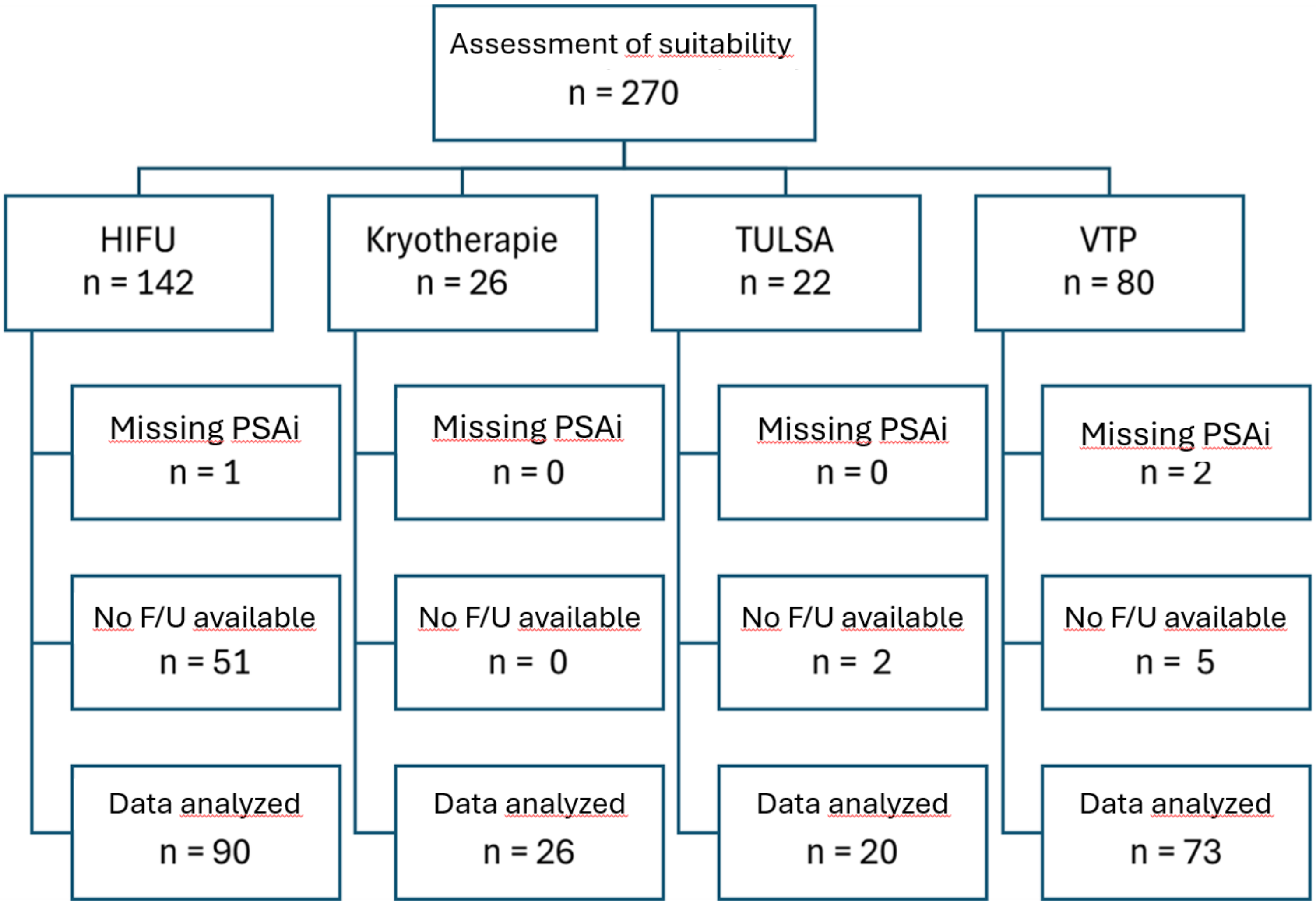
The Kaplan–Meier analysis dit not demonstrate a significant difference in progression-free survival between patients with initially suspicious versus non-suspicious MRI findings

Figure 4: Recurrence-free Survival depending on F/U-MRI

The Kaplan–Meier curve demonstrates a highly significant difference in recurrence -free survival between patients with suspicious versus non-suspicious MRI findings during follow-up.

Figure 5: Progression-free Survival, depending on F/U-MRI

The Kaplan–Meier curve demonstrates a highly significant difference in progression-free survival between patients with suspicious versus non-suspicious MRI findings during follow-up.


Assessment of suitability
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HIFU
n = 142
Kryotherapie
n = 26
TULSA
n = 22
VTP
n = 80
Missing PSAi
n = 1
Missing PSAi
n = 0
Missing PSAi
n = 0
Missing PSAi
n = 2
No F/U available
n = 51
No F/U available
n = 0
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Data analyzed
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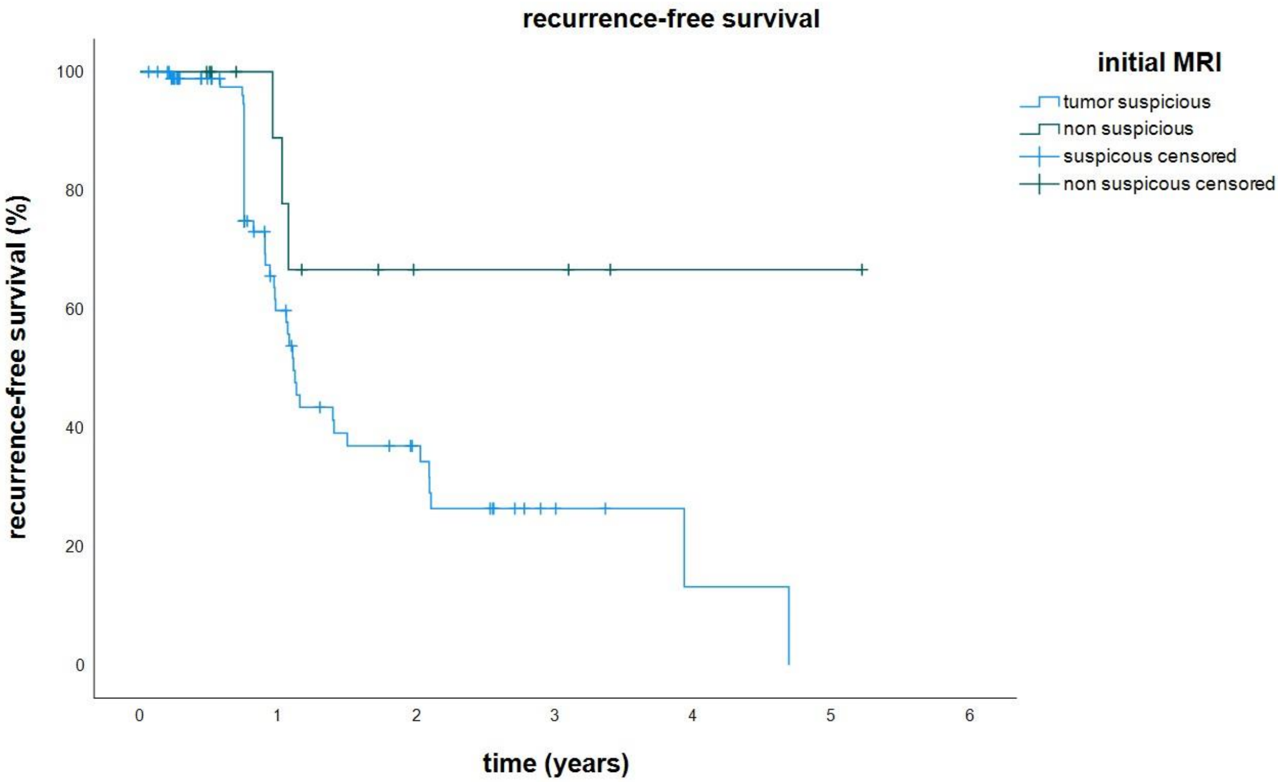
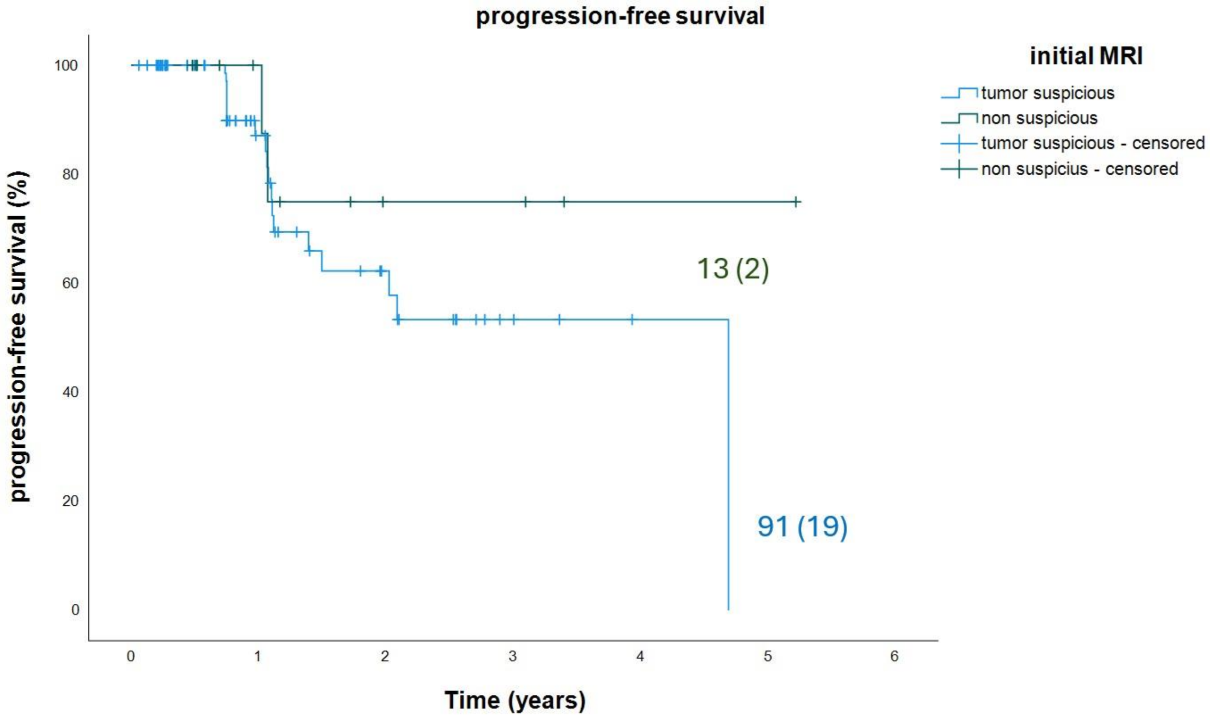


Median PCa-recurrence-free survival

Initial MRI suspicious 1.1 years (95%-CI 1.014-1.20)

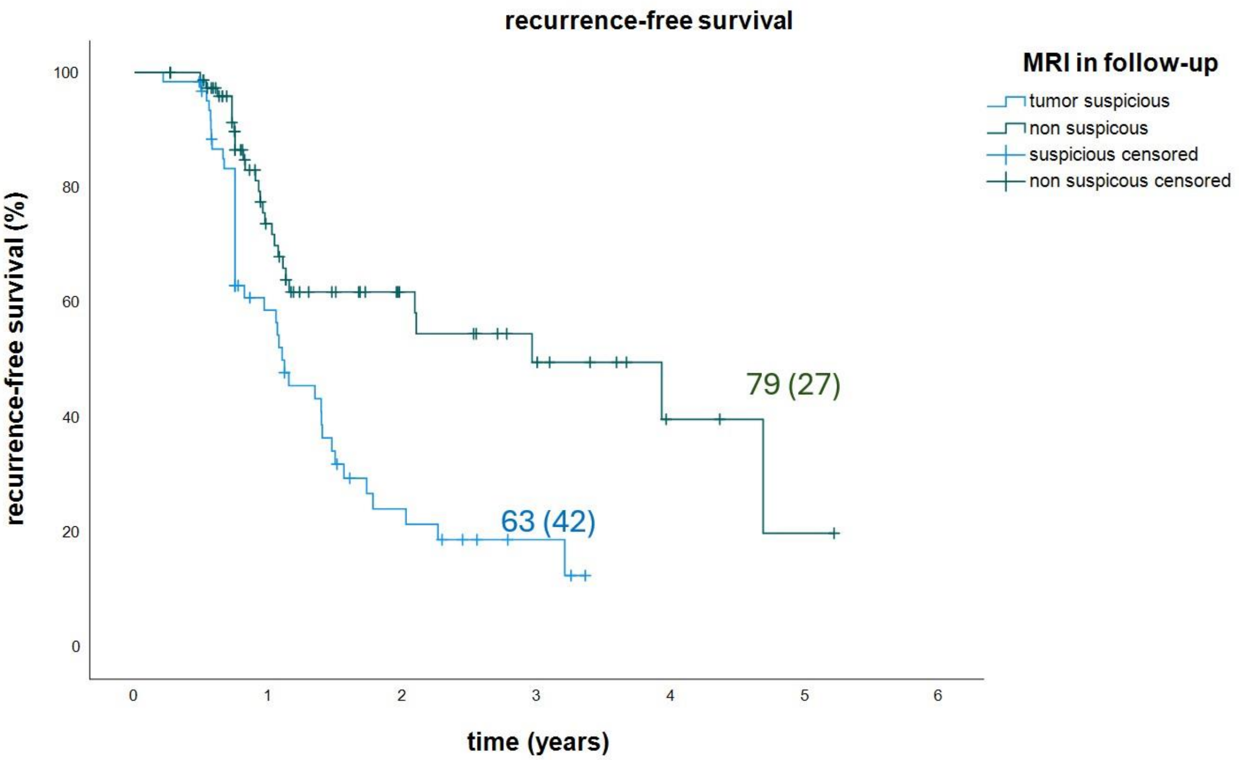
Initial MRI non suspicious NR; p=0.041



Median PCa-progression-free survival

Initial MRI suspicious 4,7 years (95%-CI NR)

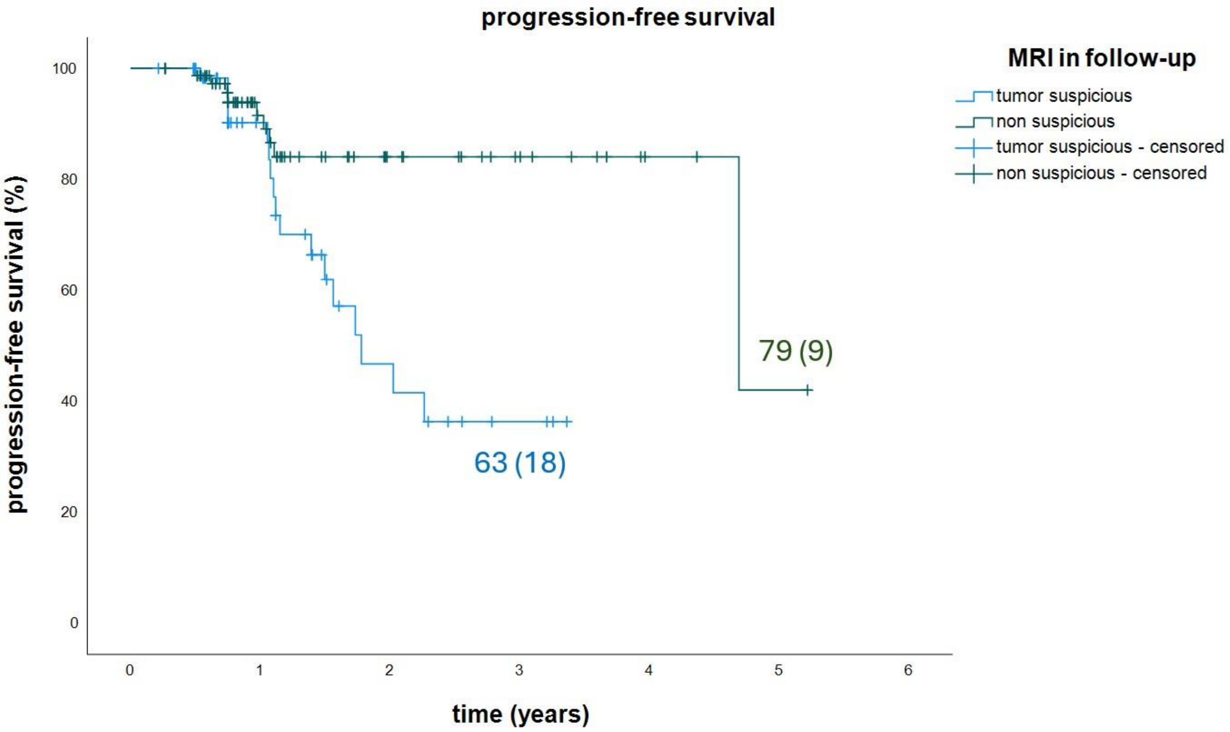
Initial MRI non suspicious NR; p=0.285



Median PCa-recurrence-free survival

MRI in follow up suspicious 1.1 years (95%-CI 0.806-1.396)

MRI in follow up non suspicious 2.9 years (95%-CI 1.341 – 4.588; p<0.001)



Median PCa--progression-free survival

MRI in follow up suspicious 1.8 years (95%-CI 1.187-2.370)

MRI in follow up non suspicious 4.7 years (95%-CI 0.000 – 9.670; p=0.004)

Table 2: Cross-Table: Initial MRI before therapy vs. MRI at first follow-Up

		MRI at first F/U			Total
		suspicious	Not suspicious	Not performed	
iMRT	suspicious	34	28	29	91
	Not suspicious (PI-RADS < 3)	1	10	2	13
	Not performed	28	41	36	105
Total		63	79	67	209

Tables:

Table 1: epidemiological data

Parameter	
Age at diagnosis (years, median, IQR)	66 (59-71)
Initial PSA (ng/ml, median, IQR)	6.40 (4.94-8.31)
prostate volume (mL, median, IQR)	40 (28-55)
PSA-density (ng/mL^2, median, IQR)	0,17 (0,11-0,26)
Pre-operative IPSS (median, IQR) (n = 174) - IPSS ≤ 7 (n, %) - IPSS 8-14 (n, %) - IPSS ≥ 15 (n, %)	6 (3-10) 100 (58) 50 (29) 24 (13)
pre-operative IIEF-5 (n = 102) - IIEF-5 ≤ 21 (n, %) - IIEF-5 > 21 (n, %)	 60 (59) 42 (41)
ISUP at diagnosis - ISUP 1 (n, %) - ISUP 2 (n, %) - ISUP 3 (n, %) - ISUP 4 (n, %) - ISUP 5 (n, %) - unknown (n, %)	 120 (58) 60 (29) 13 (6) 7 (3) 3 (1) 6 (3)
Pre-operative mpMRI - mpMRI performed (n, %) - PI-RADS 2 (n, %) - PI-RADS 3 (n, %) - PI-RADS 4 (n, %) - PI-RADS 5 (n, %)	 104 (50) 13 (13) 19 (18) 54 (52) 18 (17)
Tumor localization - right (n, %) - left (n, %) - unknown (n, %)	 78 (37) 94 (45) 37 (18)
Focal therapy modality - HIFU (n, %) - Cryotherapy (n, %) - TULSA (n, %) - VTP (n, %)	 90 (43) 26 (12) 20 (10) 73 (35)