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VALUE OF ADDITIONAL OFF-TARGET CORES IN MRI-TARGETED IN-BORE PROSTATE BIOPSY

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ABSTRACT – ***Objective:*** In this study, we evaluated whether additional contralateral off-target cores in in-bore MRI-guided prostate biopsy of unilateral suspicious lesions can improve the detection of clinically significant prostate cancer (csPCa).

Patients and Methods: In a retrospective analysis of 278 patients with in-bore targeted biopsy (ib-TB) of the prostate, we identified patients with a unilateral lesion Prostate Imaging Reporting and Data System (PI-RADS) ≥ 3 (index lesion) and a contralateral off-target core PI-RADS < 3 (n=109) or PI-RADS=3 (n=58). Patients had a mean age of 67 ± 7.8 years and a median prostate-specific antigen (PSA) density of 0.28 ± 0.39 ng/mL/ccm. We correlated the highest International Society of Urological Pathology (ISUP) grade group and the corresponding PI-RADS v2.1 score of each side of the prostate per patient.

Results: Prostate carcinoma (PCa) was present in 169 of 278 patients (60.8%), with ISUP grade groups 1, 2, 3, 4, and 5 in 48, 46, 38, 27, and 10 patients, respectively. The detection rate for csPCa was 43.5% (121 of 278 patients, including PI-RADS 3). The detection rate for the 189 patients with MRI findings of PI-RADS 4 and 5 was 84.7% for PCa overall and 63% for csPCa. No cases of prostate cancer diagnosis or tumor upgrading would have been missed if contralateral off-target cores had not been sampled.

Conclusions: Additional contralateral off-target cores do not improve diagnostic accuracy for confirming or excluding carcinoma at the patient level using ib-TB. In this cohort of 278 patients, our findings support the hypothesis that a target-only strategy in MR-guided in-bore prostate biopsy may be an effective and reliable approach.

KEYWORDS: Prostate, Biopsy, Direct in-bore, Detection rate, PI-RADS, Targets.

INTRODUCTION

Multiparametric prostate MRI has become an essential tool in the diagnosis of prostate cancer. A standardized protocol and structured reporting [Prostate Imaging Reporting and Data System (PI-RADS)] support decisions about whether to perform a prostate biopsy. Several studies[1-5] have demonstrated that MRI-targeted prostate biopsy improves the detection of clinically significant prostate cancer (csPCa; ISUP grade group ≥2). Consequently, targeted biopsy (TB) is often combined with systematic biopsy (SB) in clinical practice, which increases the total number of biopsy cores obtained[6,7].

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There are three main approaches to perform targeted prostate biopsies. In general, all biopsies are feasible *via* transrectal or transperineal access. Cognitive fusion biopsies and software-based fusion biopsies both rely on ultrasound as the imaging technique for target planning. Software-based fusion biopsies need a registration process to integrate MR and ultrasound information, with possible registration error due to deformation and movement[5,8].

In-bore prostate biopsy represents the most direct implementation of MR information during the biopsy procedure. However, because of the advanced technical requirements, the in-bore biopsy is usually limited to three to five target samples[1,5,7]. The focus on the index lesion is associated with fewer non-significant cancer findings graded according to the International Society of Urological Pathology (ISUP) grade group 1[1,3,5,9,10], though other cancer lesions may be missed without additional SB. Simultaneously, the procedure is less invasive in terms of patient comfort and the rate of complications when targets are limited to the index lesion[11].

In studies evaluating TB, it is crucial to consider if the TB is performed by fusion (fus-TB) or in-bore in the MRI scanner (ib-TB). In the literature, both techniques are referred to as MR-guided targeted biopsy. Some comparative studies[6,12,13] of fus-TB (cognitive fusion or software-based fusion) with transrectal ultrasound-guided SB favor additional systematic biopsies because fus-TB alone may miss csPCa. Nevertheless, other studies[14,15] indicate that systematic biopsy can be omitted. In contrast, studies comparing ib-TB and SB show that additional SB is of no value for the detection of csPCA[1,16] or of limited value[17] in the real in-bore biopsy setting. Recent studies[7,18] have reignited discussion about the optimal number of cores to take.

Consequently, there is no accepted or standardized biopsy strategy for the in-bore prostate biopsy. Therefore, the aim of this study was to evaluate whether additional contralateral off-target cores in MRI-guided in-bore prostate biopsy of unilateral suspicious lesions improve the detection of clinically significant prostate cancer (csPCa).

PATIENTS AND METHODS

Study design

From 2007 until 2021, MRI-guided in-bore prostate biopsies were performed in 291 consecutive patients with suspected prostate cancer. Thirteen patients were excluded due to incomplete documentation of histopathological findings.

All diagnostic and interventional MRI image sets were reviewed by a radiologist with more than 12 years' experience in prostate MRI and prostate biopsy. Marked biopsy trajectories (n=1,027) from the remaining 278 patients (2-6 cores per patient) were reanalyzed according to PI-RADS v2.1 to ensure consistency and minimize interobserver variability.

Of the 278 patients in the retrospective cohort, 109 had a unilateral index lesion (PI-RADS ≥ 3) and a contralateral "true" off-target core (PI-RADS < 3). These patients constituted the primary study cohort for the present analysis evaluating the diagnostic value of contralateral off-target sampling in the presence of a unilateral index lesion. An additional 58 patients had a contralateral lesion scored as PI-RADS 3, which we classified as an "uncertain" off-target core. These subgroups were analyzed separately to assess the diagnostic value of contralateral off-target sampling, while maintaining transparency about the heterogeneity of lesion characteristics. Patients were further subclassified according to the PI-RADS score of the index lesions (PI-RADS 3 *vs.* > 3). Sixteen patients presented with both an index lesion PI-RADS 3 and a contralateral off-target lesion rated PI-RADS 3. These cases were included in the retrospective analysis of all lesions according to PI-RADS v2.1, which in some instances differed from the original diagnostic assessment (Figure 1).

For each patient, we correlated the highest ISUP grade group with the corresponding PI-RADS score on each side of the prostate.

Patient Demographics and Clinical Data

Patients with suspicious lesions in prostate MRI were assigned to biopsy in a consensus-based decision by a radiologist and a urologist. All methods were carried out following relevant guidelines. Further systematic biopsies before or after the targeted biopsy were not subject to this study. Patients had a mean age of 67 ± 7.8 years. Median prostate-specific antigen (PSA) was 16.3 ± 27.1 ng/mL, and median PSA density was 0.28 ± 0.39 ng/mL/ccm with a mean prostate volume of 70 ± 33.7 mL.

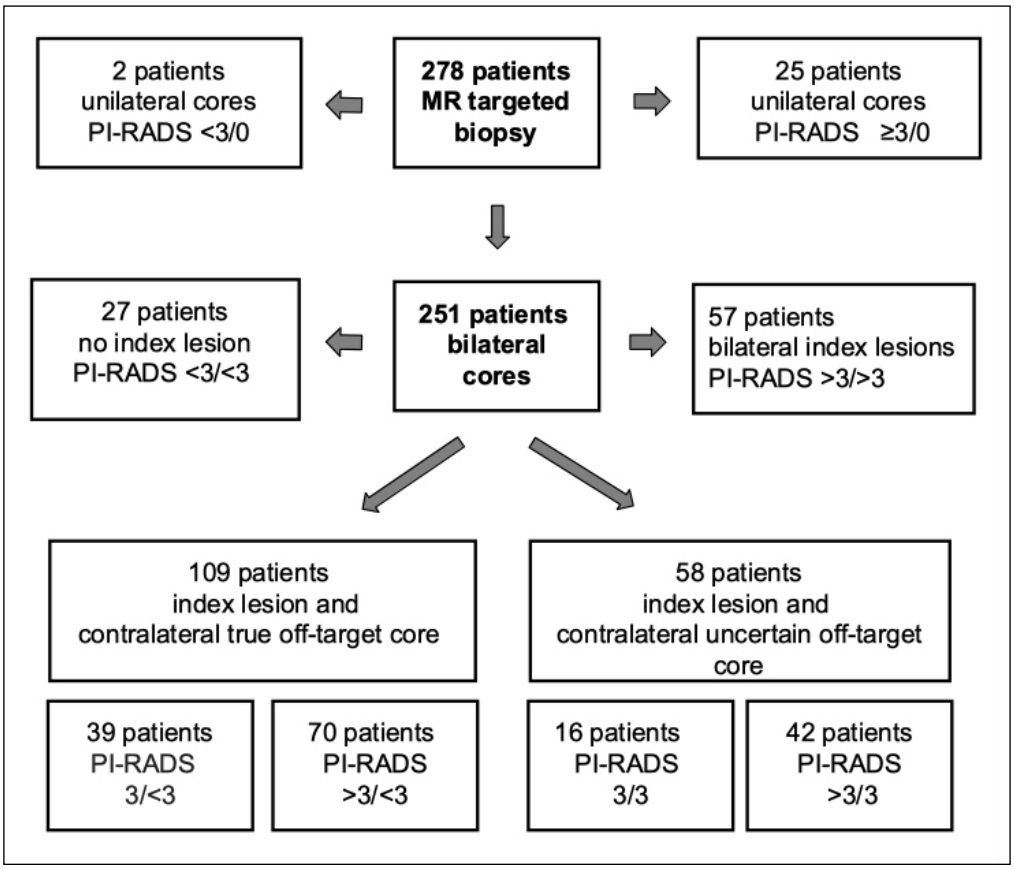

Figure 1. Flowchart of patient inclusion and group assignment. Selection process of patients undergoing MR-guided in-bore biopsy, including those with additional contralateral off-target cores.

The index lesion with the highest suspicion was targeted on the left and/or the right side of the prostate. For patients with unilateral index lesions, additional contralateral off-target cores were obtained at the discretion of the operator based on imaging findings and clinical judgment. Overall, 2-6 cores were taken per patient. In 74.5% of all patients, 3-4 cores were taken.

Multiparametric Magnetic Resonance Imaging (mpMRI) of the Prostate and In-Bore MR-Guided Biopsy

MRI was performed using a 1.5 Tesla (ESPREE, Siemens Healthcare, Erlangen, Germany) in 210 patients with an endorectal coil and a 3 Tesla (PIONEER, GE Healthcare, Chicago, IL, USA) scanner in 68 patients.

The standard protocol fulfilling the requirements of the Consensus Meeting on the Standardization of Prostate MRI and the appropriate version of the prostate imaging included T2w imaging in three planes. Diffusion weighted imaging (DWI) was performed using 4 b-values (0, 100, 800, 1,400 at 1.5 T and 0, 100, 800, 1,500 at 3 T). The apparent diffusion coefficient was calculated from b = 0, 100, and 800 s/mm^2. We used dynamic contrast enhancement (DCE) with a temporal resolution of 8.3 s on both scanners. Gadoteric acid was applied as contrast media in a weight-adapted standard dose (0.1 mmol/kg body weight) with an injection rate of 3 mL s^{-1}.

For the biopsy, the patient was positioned using a biopsy positioning device, in supine position for 1.5 T (preproduction model, Invivo, Corporation, Gainesville, FL, USA and Siemens Healthcare, Erlangen, Germany) and in prone position for 3 T (DynaTRIM, Invivo Corporation, Gainesville, FL, USA and Philips, Best, The Netherlands).

An adjustable needle guide was inserted transrectally under the control of sagittal and coronal fast imaging. Once correctly positioned, the biopsy was performed using an 18 G MR-compatible fully automatic biopsy gun.

Each biopsy procedure was documented by fast T2w imaging in the axial plane and in the sagittal or coronal plane with the needle inside the lesion (needle-control scan, Figure 2). All biopsy specimens were evaluated in the same histopathologic institute, including Gleason/ISUP grading of prostatic carcinoma. An ISUP grade group ≥ 2 was considered csPCa.

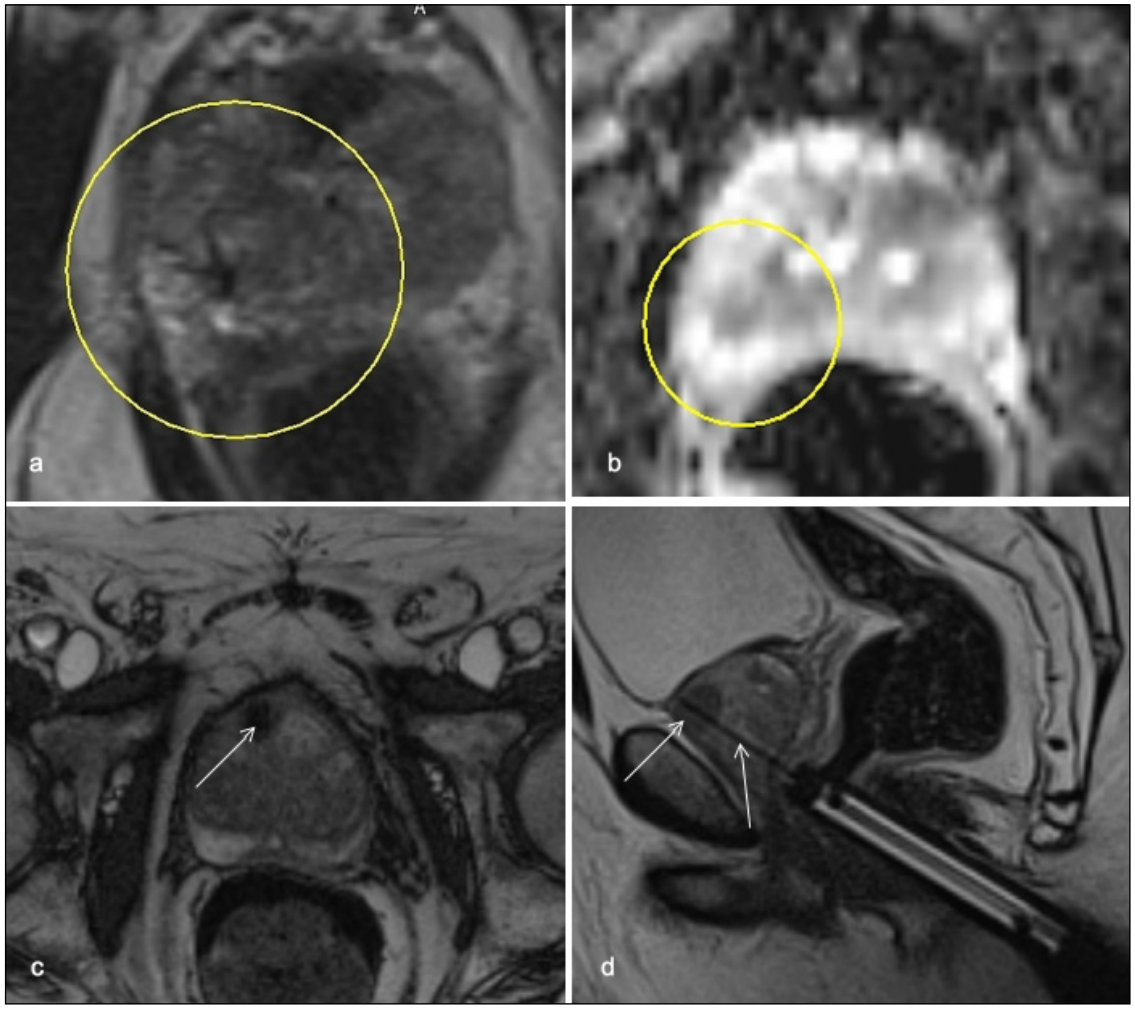

Figure 2. Needle-control scan in in-bore prostate biopsy for the monitoring of the needle position and insertion depth; (**a**) Axial T2-weighted Turbo Spin Echo image showing the needle tip (circle) within a right peripheral zone lesion; (**b**) Apparent Diffusion Coefficient map of the same patient as in (**a**), demonstrating diffusion restriction corresponding to prostate carcinoma ISUP grade 4 (circle); (**c**) Axial T2-weighted True Fast Imaging with Steady-State Free Precession image showing the needle tip (arrow); (**d**) Sagittal oblique multishot turbo spinecho BLADE image of the same patient as in (**c**), illustrating the needle trajectory with high insertion depth for an anterior located lesion (arrows), histology revealed chronic prostatitis without carcinoma.

Ethics Approval

Institutional review board approval was obtained from the Ethics Committee of Witten/Herdecke University, Germany for this retrospective study. All patients provided written informed consent for the use of their data for research purposes.

Statistical Analysis

We correlated histologic results with patient groups by PI-RADS score, separated by side. Values are presented as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate.

RESULTS

The biopsy results led to a diagnosis of prostate carcinoma in 169 of all 278 patients (60.8%), with ISUP grade groups of 1, 2, 3, 4, and 5 identified in 48, 46, 38, 27, and 10 patients, respectively. Accordingly, the overall detection rate for csPCa was 43.5% (121 of all 278 patients, including those with PI-RADS 3 lesions). The detection rate for the 189 patients with MRI findings of PI-RADS v2.1 4 and 5 was 84.7% for PCa overall and 63% for csPCa.

Bilateral cancer was found in 58 of 278 patients (20.9%). Specifically, bilateral carcinoma was present in 42 of 57 patients with bilateral index lesions with a PI-RADS category of > 2, in 6 of 109 patients with true off-target cores (PI-RADS < 3), and in 10 of 58 patients with uncertain off-target cores (PI-RADS 3).

Figure 3 provides an overview of biopsy results for patients without off-target cores, while Figure 4 presents a detailed analysis of the highest ISUP grade group and corresponding PI-RADS score for each side of the prostate in patients with off-target cores.

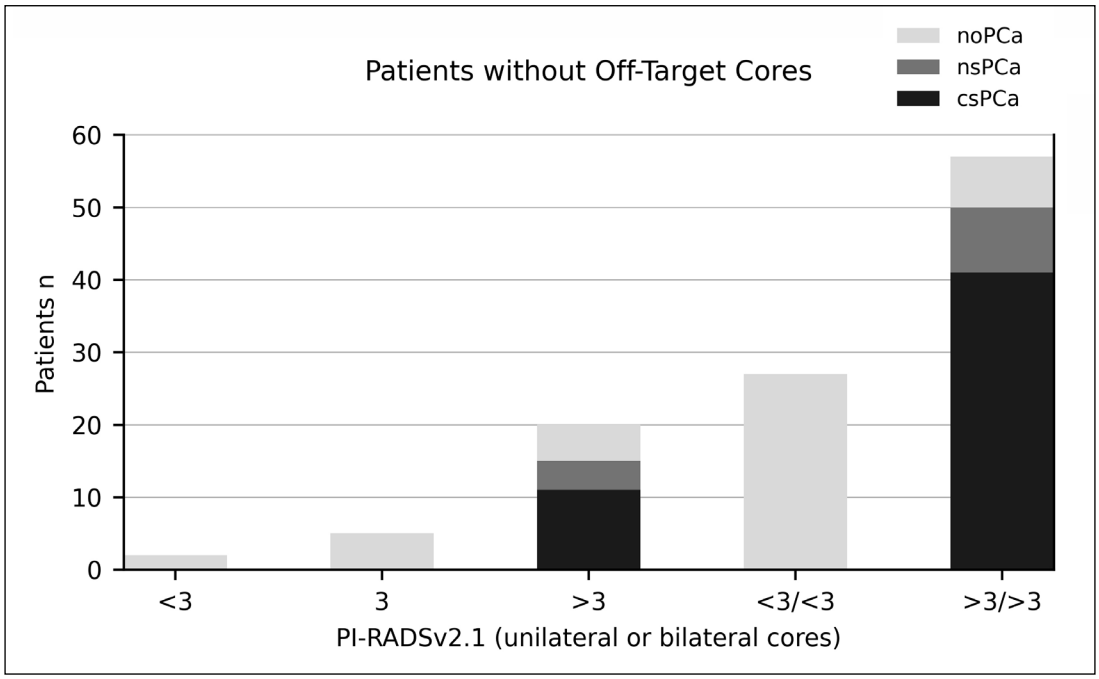

Figure 3. Biopsy results in patients without off-target cores. These patients presented either unilateral biopsy cores or bilateral cores with identical PI-RADS scores. PI-RADS scores below 3 were based on retrospective reevaluation according to PI-RADS v2.1 rating.
noPCa = no prostate carcinoma; nsPCa = non-significant prostate carcinoma (ISUP 1); csPCa = clinicallly significant prostate carcinoma (ISUP ≥ 2).

In this study, we focused on patients with bilateral cores, where an index lesion (PI-RADS ≥ 3) was combined with a contralateral off-target core (PI-RADS < 3 or PI-RADS = 3). In 16 patients, we identified a carcinoma in the contralateral off-target core. In all 6 patients with true off-target cores (PI-RADS < 3), the ISUP grade was higher on the index side than on the contralateral off-target side. Among the 10 patients with uncertain off-target cores (PI-RADS = 3), we found an ISUP 1 carcinoma on both sides in 5 patients and an ISUP 2 carcinoma on both sides in 1 patient. Consequently, no patient in this study had to upgrade the index tumor based on findings from the additional off-target core.

Table 1 presents details of patients with carcinoma-positive off-target cores.

Figure 5 illustrates the distribution of patients across four diagnostic outcome groups.

In groups 1-3, the biopsy strategy was deemed successful for confirming or excluding carcinoma on a per-patient basis.

Importantly, no patient was assigned to group 4, where a carcinoma would have been found only by the off-target cores with no carcinoma on the index side (PI-RADS ≥ 3). In this group, a waiver of contralateral cores with PI-RADS < 3 would have missed the carcinoma. Under these conditions, the off-target cores would have had an additional value.

In summary, omission of contralateral off-target cores would not have led to missed prostate cancer diagnoses or tumor upgrading in any patient within this cohort.

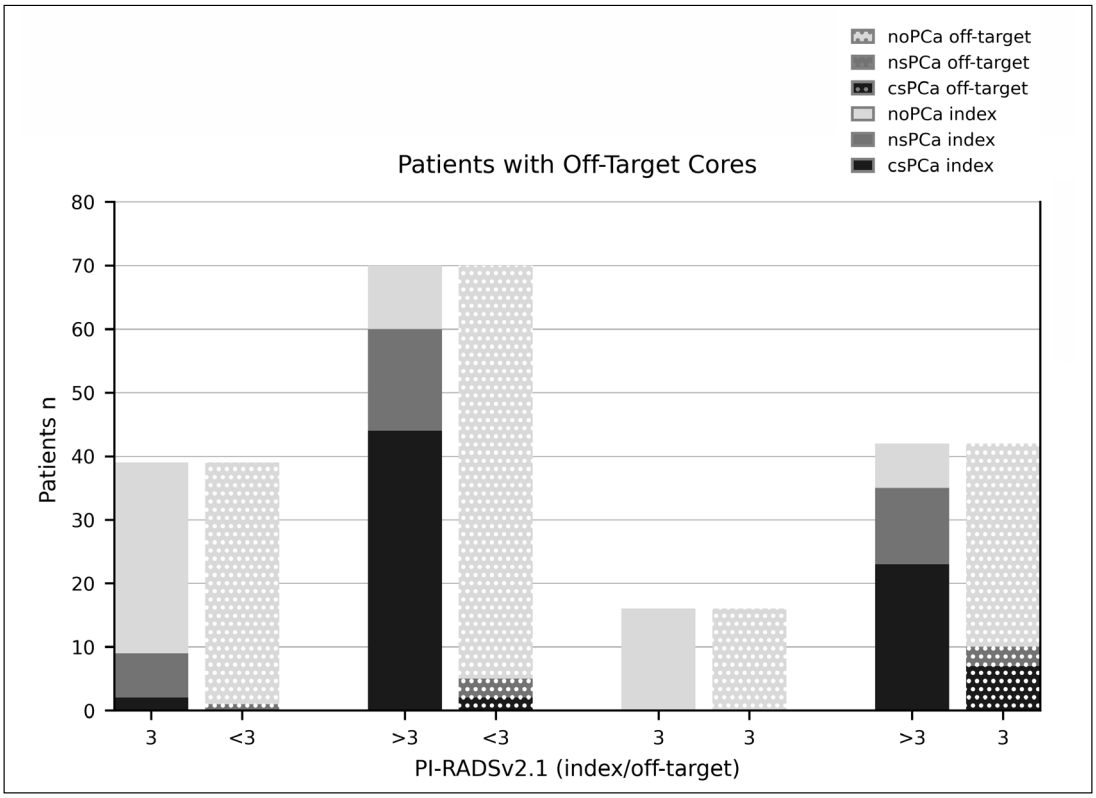

Figure 4. Biopsy results in patients with off-target cores. The first bar represents the index lesion; the second bar represents the off-target core in the same patients. Each pair of bars depicts patients with identical PI-RADS scores for index lesion and off-target lesions.
noPCa = no prostate carcinoma; nsPCa = non-significant prostate carcinoma (ISUP 1); csPCa = clinicallly significant prostate carcinoma (ISUP ≥ 2).

Table 1. Patients with prostate carcinoma-positive contralateral off-target cores.

PI-RADS v2.1 index/ off-target	Off-target	ISUP index/ off-target	Age (years)	Biopsy-naive	Prostate Volume (ml)	PSA density	Percentage PCa in off-target core	Zone
3/2	True	1/1	64	Yes	62	0.19	N/A	TZ
5/2	True	2/2	60	Yes	35	0.24	N/A	PZ
5/2	True	2/1	77	Yes	35	0.25	2	PZ
4/2	True	2/2	65	Yes	34	0.18	40	PZ
4/2	True	2/1	61	Yes	47	0.06	5	PZ
5/2	True	3/1	72	Yes	80	0.09	5	TZ
4/3	Uncertain	1/1	62	No	32	0.23	N/A	PZ
4/3	Uncertain	1/1	64	No	38	0.22	N/A	PZ
4/3	Uncertain	1/1	60	Yes	25	0.35	N/A	PZ
5/3	Uncertain	1/1	65	Yes	28	0.64	N/A	PZ
4/3	Uncertain	2/1	69	Yes	27	0.11	N/A	PZ
4/3	Uncertain	1/1	62	Yes	50	0.14	N/A	PZ
4/3	Uncertain	3/2	64	No	82	0.12	N/A	PZ
4/3	Uncertain	4/3	77	Yes	32	0.57	5	TZ
4/3	Uncertain	4/3	68	Yes	33	0.13	30	PZ
5/3	Uncertain	2/1	77	Yes	35	0.25	2	PZ

PI-RADS v2-1 = Prostate Imaging Reporting and Data System version 2.1; ISUP = International Society of Urological Pathology grade group; PSA = prostate-specific antigen; PCa = prostate carcinoma, TZ = transition zone; PZ = peripheral zone, N/A = not available.

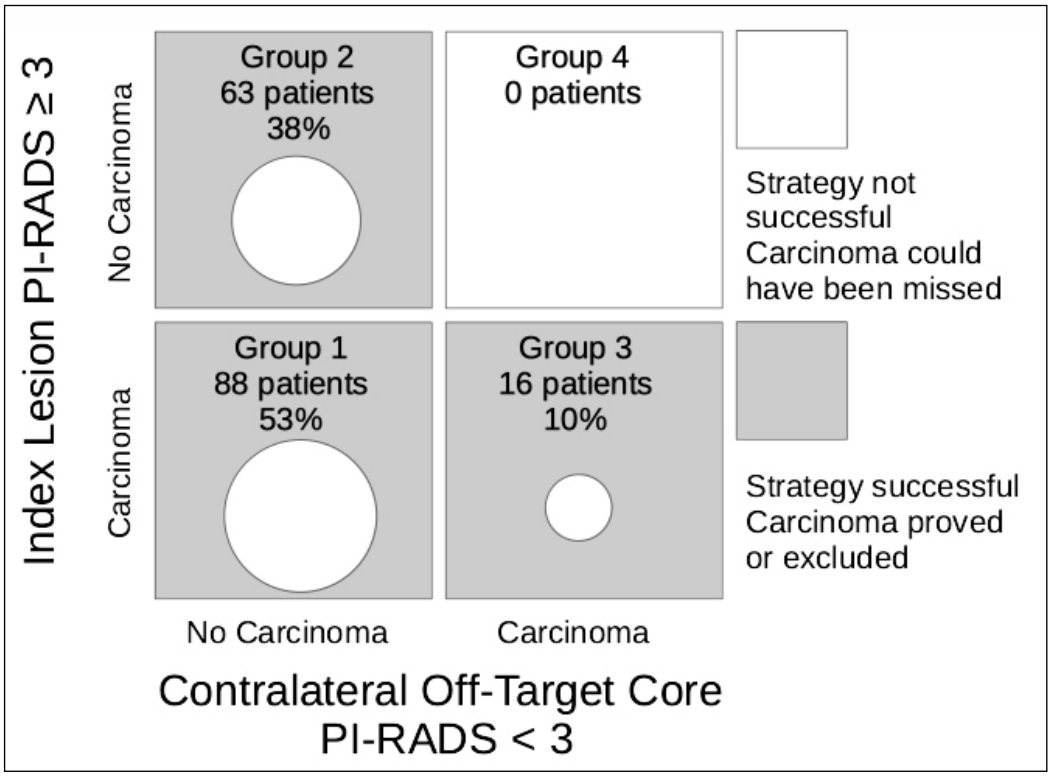

Figure 5. Patient group assignment.
Group 1: expected results with carcinoma on the index side; Group 2: no carcinoma despite PI-RADS 4 or 5 finding; Group 3: carcinoma present on both index and off-target sides; Group 4: no carcinoma on the index side but on the off-target side. Contralateral off-target cores provided no additional diagnostic value, as no patient in Group 4 would have had a carcinoma missed by omitting contralateral cores with PI-RADS < 3.

DISCUSSION

In our study population, additional contralateral off-target cores in MR-guided prostate biopsy did not provide additional diagnostic value for confirming or excluding carcinoma at the patient level. Moreover, taking additional contralateral off-target cores did not result in any upgrading of the index tumor in cases of bilateral carcinoma.

In contrast, our data support that a target-only strategy for in-bore prostate biopsy is successful in patients with mpMRI findings of PI-RADS v2.1 4 and 5, with an overall detection rate of 84.7% and a detection rate for csPCA of 63%. These findings are consistent with previous studies[3,4], and validate the accuracy of our diagnostic and interventional workflow, including the use of needle-control scans.

Despite the acknowledged limitations of the retrospective design and the single-center setting, the present study provides clinically relevant real-world data on the diagnostic yield of contralateral off-target sampling in MRI-guided in-bore prostate biopsy and contributes to the ongoing discussion on how to optimize biopsy strategies while minimizing unnecessary tissue sampling.

There are a few studies in the literature that address the optimal number of cores in targeted prostate biopsy.

Our results are consistent with those of Prince et al[1], who demonstrated no additional value of systematic off-target sampling in a comparative study of ib-TB and fus-TB combined with SB in 286 men with lesions PI-RADS 4 and 5. Notably, ib-TB showed a higher detection rate for all cancers (84%) and for ISUP grade ≥ 2 (68%). Although two to four cores were obtained per target, only the first core of the dominant lesion was analyzed. The authors concluded that a target-only in-bore prostate biopsy could be considered clinically appropriate.

Lazarovich et al[17] combined systematic and targeted in-bore biopsy (ib-TB and ib-SB), performing a median of five cores per lesion and an additional 12-core systematic in-bore biopsy under general anesthesia. They also analyzed 124 patients with unilateral suspected PCa and compared SB and TB results. In contrast to our findings, they identified four patients (2.1%) in whom csPCa was detected only

through systematic contralateral off-target cores of the lobe and one patient with upgrading of clinically insignificant PCa to csPCa by contralateral off-target sampling. Nevertheless, ib-TB achieved a csPCa detection rate of 96%.

A recent review[7] reported no significant difference between ib-TB and fus-TB, and additional SB in cognitive or software-based fus-TB did not improve csPCa detection rates.

Similarly, the FUTURE trial[2] compared three MRI-guided biopsy techniques and found no significant difference among software-based fus-TB, cognitive fus-TB, and ib-TB for the detection of overall PCa or csPCa. However, the median number of biopsy cores differed – four for software-based fus-TB, three for cognitive fus-TB, and two for ib-TB.

Although data on ib-TB compared with SB remain limited, several studies have evaluated fus-TB relative to SB.

Rouviere et al[6] in a comparative study of 251 patients undergoing transrectal ultrasound (TRUS)-SB and fus-TB concluded that systematic biopsy remains necessary, as significant cancer would have been missed in 5.2% of patients without SB. Nonetheless, they found a higher csPCa detection rate with TB (32.2%) compared with SB (29.9%), and csPCa was detected exclusively by fus-TB in 7.6% of patients.

Another study[13] found additional csPCa in 8.8% of 2,103 patients *via* SB, whereas Patel et al[14] reported an additional 4.2% in 240 patients not identified by fus-TB alone. Prince et al[1] discussed whether a higher number of off-target cores might compensate for reduced precision in TRUS fusion biopsies. Consequently, some authors[18-20] have suggested adding perilesional cores in TRUS biopsy or performing regional saturation biopsy[21] with mixed outcomes.

Hugosson et al[15] investigated a TRUS target-only strategy with cognitive fusion in a screening setting involving a population of 37,887 subjects. Among 11,986 participants in the experimental group, clinically insignificant PCa was detected by cognitive fus-TB in 0.6% compared with 1.2% in the reference group of 5,994 participants who underwent combined cognitive fus-TB and SB. The relative risk of csPCa detection was higher in the target-only group than in the reference group (0.81 *vs.* 0.6). Ten participants had csPCa detected solely through systematic biopsy; however, these cases were of intermediate risk and low tumor volume and were managed with active surveillance. The authors concluded that cognitive fus-TB without SB in men with elevated PSA reduces overdiagnosis but carries a minor risk of delayed detection of intermediate-risk cancers.

Several authors[22,23] have proposed abandoning systematic biopsy in patients with PI-RADS 5 lesions, as TRUS-SB did not improve overall prostate cancer detection compared with TRUS-TB alone.

Klotz et al[24] further suggested omitting TRUS-SB in favor of follow-up diagnostic MRI. In a cohort of 453 patients, no difference in csPCa detection was observed between those undergoing follow-up MRI with TRUS-TB as needed and those undergoing TRUS-SB, while 38% of men avoided an initial biopsy.

To optimize prostate biopsy strategies, the objectives of cancer detection must be clearly defined. The current goal is to maximize detection of csPCa while minimizing the diagnosis of clinically insignificant PCa.

Emerging concepts of focal therapy may require more precise mapping of relevant lesions within each lobe or even per prostate quadrant[25]. At the same time, cost-effectiveness and the potential complications associated with unnecessary biopsies or excess sampling must be considered.

Optimizing prostate biopsy may depend on a tailored strategy that uses factors such as PSA density, lesion size/volume, and lesion location to refine candidate selection for a target-only approach. In this context, reducing unnecessary biopsy cores without compromising the detection of clinically significant prostate cancer may represent an important step toward more patient-centered and risk-adapted diagnostic strategies.

Within this framework, the clinical significance of PI-RADS 3 lesions and the role of MRI in active surveillance[26] warrant critical reevaluation. A target-only approach appears appropriate for patients with well-defined PI-RADS 4 or 5 lesions. In patients at higher risk of bleeding or infection, ib-TB offers additional advantages due to its precision and minimally invasive nature. Determination of minimum lesion size thresholds could be refined using volumetric analysis supported by artificial intelligence tools.

MR-guided targeted biopsies should clearly be labeled as ib-TB or fus-TB. However, regional disparities in technical infrastructure and specialized expertise remain limiting factors at present.

Limitations

This study has several limitations that should be considered. First, it is a retrospective, single-center analysis, which may limit the generalizability of the findings. The inclusion period spanned from 2007 to 2021, during which technological developments in MRI hardware, software, and image interpretation could have influenced lesion detection and characterization. To mitigate this, all MRI and biopsy data-

sets were retrospectively re-evaluated according to PI-RADS v2.1 to ensure consistency. Second, only a single contralateral off-target core was obtained per patient. The limited number of off-target cores did not allow for subgroup analyses (e.g., by PI-RADS category, PSA density, or lesion location). Additional contralateral sampling could be a future avenue for improving the detection of small yet clinically relevant lesions. Third, the decision to obtain contralateral off-target cores was not strictly protocol-driven but partly based on operator discretion, which introduces a potential selection bias. Nonetheless, this approach reflects real-world clinical practice, where biopsy strategies are often individualized based on imaging findings and clinical judgment. Finally, whole-mount histopathological correlation was not available; however, all cores were carefully analyzed, and PI-RADS 1-2 lesions are known to have a high negative predictive value[27], supporting the reliability of the present findings. Therefore, the findings should be interpreted as hypothesis-generating and warrant confirmation in prospective multicenter studies.

CONCLUSIONS

In this cohort of 278 patients, the addition of contralateral off-target cores in MR-guided in-bore prostate biopsy did not demonstrate a clinically relevant additional diagnostic benefit in confirming or excluding prostate cancer at the patient level. Despite the retrospective single-center design and the limited number of off-target cores, the findings provide real-world evidence supporting a target-only approach for well-defined PI-RADS 4-5 lesions. Further prospective multicenter studies are warranted to confirm these results and to optimize individualized biopsy strategies that balance diagnostic accuracy, patient comfort, and procedural efficiency.

Authors' Contributions:

Marietta Garmer: protocol/project development, manuscript writing, data collection and management, data analysis.
Dietrich Grönemeyer: project development, manuscript editing.
Christin Hoffmann: data collection, data analysis, manuscript editing.
Dörthe Schaffrin-Nabe: data interpretation, manuscript editing.
Patrick Haage: data interpretation, manuscript editing.
Lars Kamper: supervision, manuscript editing.
All authors reviewed the final manuscript.

Conflict of Interest:

The authors have no relevant financial or non-financial interests to disclose.

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Ethics Approval:

This study was performed in accordance with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Witten/Herdecke (Ethical Approval 48/2019, released 2019-06-06). An amendment to the original ethics approval was obtained to extend the period covered by the retrospective data collection.

Data Availability:

Data can be obtained upon request from the corresponding author.

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