International Urology and Nephrology (2022) 54:2477–2483
https://doi.org/10.1007/s11255-022-03309-y

UROLOGY - ORIGINAL PAPER

Evaluation of systematic prostate biopsies when performing transperineal MRI/TRUS fusion biopsy with needle tracking—what is the additional value?

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Received: 31 May 2022 / Accepted: 14 July 2022 / Published online: 25 July 2022

Abstract

Purpose To evaluate the additional value of systematic biopsies (SB) when performing transperineal MRI/TRUS fusion biopsies (MRI/TRUS TPBx) with needle tracking.

Methods From January 2019 to March 2021 969 Patients after a MRI/TRUS TPBx were evaluated separately for target biopsies (TB) and systematic biopsies regarding PCa detection and PCa risk evaluation. Needle tracking in the axial sequences of multiparametric MRI was used to assess the localisation of the detected PCa in the biopsy cores related to the reported PI-RADS lesions.

Results The overall cancer detection rate (CDR) for PCa and clinically significant (cs) PCa (ISUP ≥ 2) with the combination of TB and SB were 66 and 49%. TB detected 46% csPCa and SB 22% csPCa. SB identified 1.5% additional csPCa outside of the reported PI-RADS lesions. 16 patients (1.7%) showed a relevant upgrading from clinically insignificant PCa in TB to csPCa. In 736 patients with unilateral suspicious lesions on MRI, 145 patients (20%) were detected with contralateral PCa-positive SB. 238 patients (25%) showed PCa positive systematic biopsy cores outside of the described PI-RADS lesions.

Conclusions Needle tracking optimizes the 3D-localisation of cancer in the prostate. Our results show that the added value of SB with a reduced systematic biopsy scheme is low with regard to prostate cancer (PCa) detection and PCa risk evaluation. However, there is a relevant added value for localizing multifocal PCa in the primary diagnostic by a MRI/TRUS fusion biopsy of the prostate.

Keywords Magnetic resonance imaging-ultrasound fusion targeted biopsy · Prostate cancer · Transperineal prostate biopsy · Systematic prostate biopsy · Prostate imaging reporting and data system

Introduction

Establishing the multiparametric magnetic resonance imaging (mpMRI) for diagnosis of prostate cancer (PCa) and the subsequent implementation of MRI/TRUS fusion biopsy of the prostate improved the detection of clinically significant prostate cancers (csPCa) [1–6]. The most recent European Association of Urology guidelines recommend systematic in addition to targeted biopsies when performing MRI/TRUS fusion biopsies in biopsy naive men [7]. This aims to minimise the proportion of missed csPCa [8]. However, the additional systematic biopsies (SB) also detect more non-significant tumours, which increases the risk of overtreatment [9, 10]. Therefore, performing additional SB is debated controversially.

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Current fusion systems enable precise localisation and retrospective comprehension of prostate biopsies using needle tracking. This new technique provides the user to exactly document the position of cancer-cores in the prostate and analyse the locational relationship to the MRI-suspected lesions.

The aim of this study is to evaluate the additional value of SB when performing transperineal MRI/TRUS fusion biopsies (MRI/TRUS TPBx) with needle tracking.

Methods

The data collection of the retrospective study was according to the guidelines of the working group of the Standards of Reporting for MRI-targeted Biopsy Studies (START) of the Prostate. An ethics approval was assigned by the ethics committee of the Berlin Medical Association (Eth-27/19) and the data security was reviewed by the data security management of the Vivantes Hospital Group. All study participants have signed an informed consent.

Study population

From January 2019 to March 2021, 1.098 patients were screened for the study. In all included patients a TPBx in the Department of Urology of the Vivantes Klinikum Am Urban by an experienced urologist (KG) was performed. Patients were referred by their treating urologist due to an elevated PSA level, a suspicious digital rectal examination or a suspicious MRI and the indication for a prostate biopsy was reviewed by a senior urologist. 969 patients with a combination of systematic (SB) and targeted biopsies (TB) were finally analysed (Fig. 1). 102 patients received isolated SB, 16 patients received targeted biopsies only and 11 patient were not included in the study because of insufficient MRI quality.

Multiparametric magnetic resonance imaging

All patients received a mpMRI prior to biopsy at a total of 27 different radiological sites. 1.5 and 3 Tesla scanners with a pelvic phased array surface coil were used. Minimal technical requirements for MRI sequences included axial T1-weighted-, axial and one further orthogonal plane T2-weighted-fast spin-echo sequences, a diffusion weighted sequence with a minimum of two *b* values (one low *b* value of 0–100 s/mm2 and one high *b* value of 800–1500 s/mm2) and calculation of an ADC map. Dynamic contrast enhancement imaging with a gadolinium-based contrast agent was used according to the PI-RADS recommendations. MRIs were evaluated according to PI-RADS (Prostate Imaging-Reporting and Data System) version 2.0 and version 2.1 by the consultant senior radiologists of the related site [11]. Most of the MRIs were evaluated according to PI-RADS 2.1 due to the update of PI-RADS in March 2019 at the beginning of the study period. MRIs with a PI-RADS $\geq$3 were considered suspicious with the recommendation for prostate biopsy. One urologist (KG) with an expertise of more than 2.000 performed biopsies marked the suspicious lesions in the MRI. For this purpose, the DWI- and T2-sequences were evaluated by the urologist on the basis of the radiological findings. PI-RADS lesions in the MRI were contoured an the maximal axial diameter was measured with the Trinity software.

Biopsy technique

For MRI/TRUS-TPBx the fusion system Koelis Trinity® with a 3D endocavity side-fire ultrasound probe, a linear grid and a probe holder (SteadyPro®) were used. The majority of procedures were performed under local anesthesia. The perineum was prepared with octenidine dihydrochloride/phenoxyethanol (Octenisept, Schülke, Germany). The local anesthesia was initiated with the infiltration of the perineal subcutaneous tissue with 20 ml 0.5% xylocaine solution with a 27 ga subcutaneous needle in the lithotomy position. Thereafter, 20 ml of 1% xylocaine solution were injected

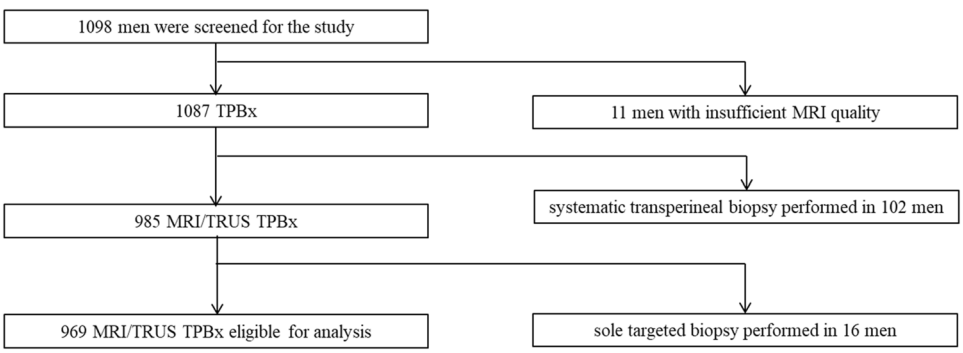

Fig. 1 Patient inclusion

with a spinal needle (22 ga × 17.8 cm, Becton, Dickinson and Company, USA) under ultrasound guidance bilaterally intramuscular into the levator ani muscle and as an apical periprostatic block. The previously imported MRI sequences (T2, DWI) were fused with the created TRUS-3D model of the prostate after contouring the prostate organ margins. The MRI lesions were superimposed onto live ultrasound images using elastic software fusion. Thereafter, 2–3 targeted biopsies from every suspicious lesion and SB cores were performed with a single-use biopsy gun (cutting length of 25 mm, Bard, USA). For SB, the target regions were omitted. The scheme for SB is demonstrated in Fig. 2. All biopsies were performed by one urological senior physician (KG). The biopsy technique was previously described in a paper by our research group [12]. The localisation of the targeted and systematic prostate biopsies were registered by organ based tracking in a 3D prostate model. For needle tracking, a 3D registration of the prostate volume was performed by automatically compensating for prostate motion after each single biopsy and the biopsy needle was marked in this 3D model (Koelis Organ Based Tracking®Technology). The image fusion of ultrasound- and MRI-sequences enabled the visualisation of the biopsies cores in the MRI. According to Koelis, the standard deviation of localisation accuracy in case of a correct image fusion is 2.3 mm [13]. The visualisation of the biopsy cores in the MRI helps to accurately target suspicious areas and avoids re-biopsy from areas that have already been biopsied. The histological evaluation was performed according to the International Society of Uropathology (ISUP 1–5). Prostate cancer with an ISUP grade ≥2 was classified as csPCa [21].

Evaluation of the systematic biopsies

After importing the histological results into the biopsy protocols, the cancer cores were labelled in colour depending on cancer detection in the 3D prostate model. The PCA positive SB were evaluated based on their location to the MRI-defined lesions. An analysis was made to define cancer detection rates (CDR) of biopsies from MRI-suspicious lesions vs. biopsies from outside these lesion (Fig. 3).

Statistical analysis

Statistical analysis of the study data was performed using SPSS Statistics Version 24.0 (IBM Corp., Armonk NY,

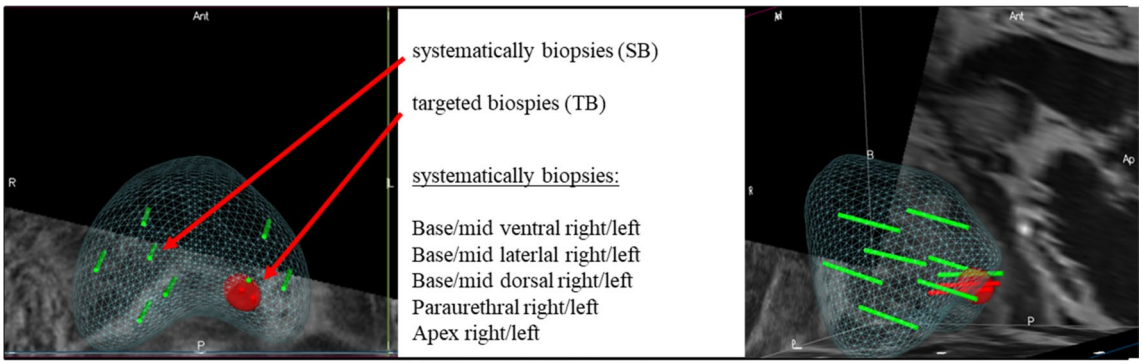

Fig. 2 Scheme of systematically biopsies

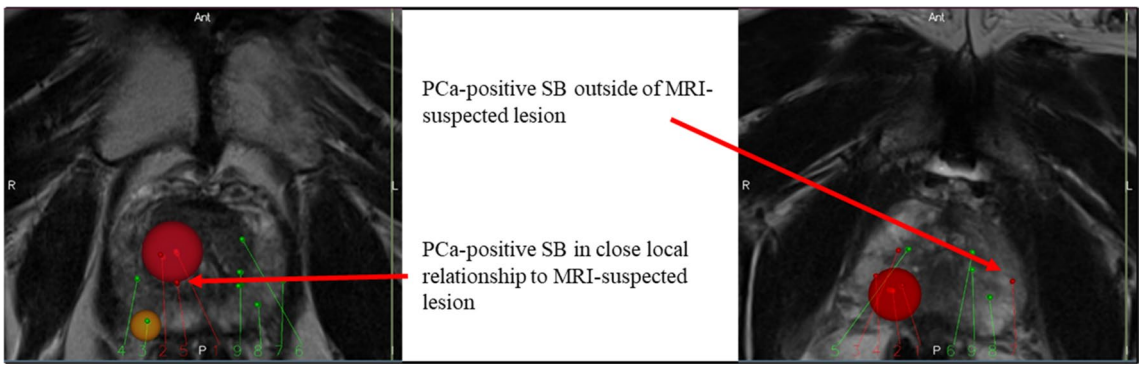

Fig. 3 Localisation of systematically biopsies depending on PI-RADS-lesion

USA). Categorical variables were reported as absolute and relative frequencies. Continuous variables were checked for normal distribution using the Kolmogoroff–Smirnov test. All continuous parameters were non-normally distributed; therefore, the median and the interquartile range (IQR) were calculated. The overall CDR and the detection of csPCa for TB, SB and the combination TB and SB were separately measured.

Results

Patient demographics

The median age, initial PSA and prostate volume were 68 years, 6.72 ng/ml and 45 ml, respectively. 151 patients (16%) showed a suspicious digital examination. 568 (59%) patients underwent a primary biopsy, 401 (41%) had one or more previous biopsies and 115 (12%) patients received the re-biopsy as part of an active surveillance protocol. TPBX was performed under local anaesthesia in 931 patients (96%) and in 862 patients (89%) without antibiotic prophylaxis. Table 1 summarises the clinical parameters.

Table 1 Patient demographics and clinical parameters

No. pts	969
Age	
Median (IQR)	68 (62–74)
PSA before biopsy (ng/ml)	
Median (IQR)	6.72 (4.83–9.99)
Prostate volume (ml)	
Median (IQR)	45 (32–65)
Clinical stage	
cT1c	818 (84%)
≥cT2a	151 (16%)
absolute (relative) frequency	
Primary biopsy	
Secondary biopsy	568 (59%)
≥2 pre-biopsies	302 (31%)
Active surveillance	99 (10%)
absolute (relative) frequency	115 (12%)
TPBX	
In local anesthesia	931 (96%)
In general anesthesia	38 (4%)
Without antibiotic prophylaxis	862 (89%)
Absolute (relative) frequency	
PI-RADS	
No PI-RADS	
2	24 (3%)
3	45 (4%)
4	206 (21%)
5	438 (45%)
Absolute (relative) frequency	256 (26%)
Total biopsies per patient	
Number of TB per patient	4 (3–5)
Number of SB per patient	6 (5–7)
Median (IQR)	

PSA Prostate-specific antigen, *IQR* Interquartile range, *TPBX* Transperineal prostate biopsy

PCa detection

The overall cancer detection rate for PCa and csPCa with the combination of TB and SB were 66% (640) and 49% (478), respectively. TB detected 61% (594) PCa overall and 46% (447) csPCa. The SB identified 36% (346) PCa overall and 22% (211) csPCa. Overall PCa detection rates for PI-RADS 2, 3, 4 and 5 were 29% (13/45), 36% (74/206), 71% (309/438) und 88% (226/256), respectively. Table 2 demonstrate the detection rates for PCa of TB and SB based on PI-RADS classification.

Systematic biopsies

Compared to the targeted biopsies, the SB detected a total of 46 (5%) additional prostate cancers, of which 15 (1.5%) were csPCA. All 15 csPCa in the SB were detected in regions other than classified as suspicious on MRI. 10 (67%) of these patients had a PI-RADS 3-lesion, two (13%) a PI-RADS 4-lesion, one (7%) a PI-RADS 5-lesion and two (13%) a suspicious lesion without PI-RADS-scoring. 14 patients showed an upgrading from ISUP 1 PCa in TB to ISUP 2 in SB and two patients from ISUP 1 in TB to ISUP>2 in SB. Five of 16 patients (31%) with an ISUP upgrade in the SB had cancer cores in the area of the suspicious lesion on MRI. Table 3 shows the distribution of the ISUP grading of the detected prostate carcinomas.152 Patients (16%) showed PCa positive systematic biopsy cores in close local relationship to the described PI-RADS lesions and 238 (25%) outside of the described PI-RADS lesions. In case of close local relationship to the PI-RADS lesions, 24% (36/152) ISUP 1 PCa were detected. In case of no local relationship to the PI-RADS lesions, 50% (118/238) of ISUP 1 PCa were found in the SB. In 736 patients with unilateral suspicious lesions on MRI, 145 patients (20%) were detected with contralateral PCa-positive SB. 75 (52%) of these PCas were clinically significant. 56 of 228 (25%) patients with confirmed ISUP 1 and 2 PCa in the targeted biopsies and an unilateral suspicious MRI lesion showed PCa-positive contralateral SB. 21 (38%) of these tumours were clinically significant. In this subgroup, 10 (4%) ISUP>2 PCa were missed by the targeted biopsies.

Table 2 Overall CDR and detection of csPCa depending on PI-RADS

	CDR	csPCa (ISUP ≥ 2)
PI-RADS 2 ($N=45$)		
TB	11 (24%)	4 (9%)
SB	7 (16%)	1 (2%)
absolute (relative) frequency		
PI-RADS 3 ($N=206$)		
TB	52 (25%)	30 (15%)
SB	51 (25%)	27 (13%)
absolute (relative) frequency		
PI-RADS 4 ($N=438$)		
TB	293 (67%)	218 (50%)
SB	157 (36%)	94 (21%)
absolute (relative) frequency		
PI-RADS 5 ($N=256$)		
TB	222 (87%)	186 (73%)
SB	124 (49%)	85 (33%)
absolute (relative) frequency		

CDR Cancer detection rate, *TB* Targeted biopsy, *SB* Systematic biopsy

Discussion

The special aspect of this study is that all transperineal MRI/ultrasound fusion biopsies of the prostate were performed with needle tracking. This enables the precise localisation of the systematic and targeted biopsies in the MRI sequences. This documentation provides an accurate evaluation of the positional relationship of PCA-positive biopsies to the described PI-RADS lesions in a robust patient cohort. Other studies have only investigated the additional PCa detection of the SB [3, 14]. In primary prostate cancer diagnosis, PCa detection, accurate risk evaluation of PCa and localisation of PCa are essential for an appropriate PCa treatment plan.

PCa-detection

In the current cohort we found an overall detection rate for PCa of 66% and for csPCa of 49% with the combination of SB and TB. The detection rate of SB alone for csPCa was 22%. In the analysis by Lee et al. the detection rate of SB was corrected for the proportion of SB that included the target areas of the MRI. This resulted in a PCa detection rate of 21% for SB alone [15]. These results are similar to our analysis, because the MRI target areas were omitted in the SB scheme. Our detection rates of the TB for PI-RADS 3, 4 and 5 lesions with 25, 67 and 87%, respectively, were comparable to other studies [3, 14]. The MRIs of our study cohort were performed in 27 radiological institutes with differing expertise in the field of prostate MRI evaluation. Due to the inhomogeneous quality of the MRI sequences and reporting, detection rates may have been influenced. In addition, the detection rate may have been biased by the use of 1.5 and 3 Tesla MRI scanners [16]. Nevertheless, MRI quality was not the focus of this analysis, so the influence on the endpoints can only be assumed. TB missed 46 (5%) of the tumours overall and 15 (1.5%) of csPCa. In other studies, the additional detection of csPCa by combining SB and TB is up to 10% [14, 17–21]. In the current study a reduced scheme of SB was implemented by avoiding unnecessary additional biopsies in the area of MRI-suspected lesions that were covered by the targeted biopsies. Therefore a median of only 6 SB were taken. Compared to the standardized 10 or 12 biopsy schemes of the studies mentioned above, our detection rates in the SB are expected to be lower and comparison is challenging. Nevertheless, in our cohort of 969 patients, overall PCa detection rates were comparable to other studies [3, 18]. Therefore, our study shows a very low added value of our reduced scheme of SB for the detection of prostate cancer in general.

Table 3 Comparison of ISUP Detection in TB and SB

	SB No PCa	SB ISUP 1	SB ISUP 2	SB ISUP 3	SB ISUP 4	SB ISUP 5
TB No PCa	329	31	9	3	3	0
TB ISUP 1	77	54	14	1	1	0
TB ISUP 2	79	24	45	10	2	0
TB ISUP 3	65	13	24	31	4	1
TB ISUP 4	58	11	10	8	23	3
TB ISUP 5	15	2	2	1	6	10

TB Targeted biopsies, *SB* Systematic biopsies

PCa risk-classification

A sufficient risk evaluation of PCa for further treatment planning is essential. In our cohort, only 16 patients (1.7%) showed a relevant upgrading from clinically insignificant PCa in TB to csPCa by SB. Ahdoot et al. [18] described an upgrading from ISUP 1 to an ISUP greater than 1 in 2.8% of cases. The reduced scheme of systematic biopsy performed in our study could be the reason for the relatively low rate of upgrading. In the subgroup of patients with evidence of csPCa in TB, 20 patients (2%) had a more aggressive tumor on SB. Ahdoot et al. [18] also reported an upgrading of 2% in the cohort of patients with csPCa in TB. A relevant upgrading on additional SB occurred in only 1.7% of the patients in our cohort.

PCa localisation

Needle tracking demonstrated that all 15 (1.5%) csPCa, which were missed by TB, were located outside the described suspicious lesions in the MRI. These PCa were not detected in the MRI and were only located in the areas of randomised biopsies. Matsouka et al. [22] also detected 5% of csPCA by SB outside the MRI target areas. In the Promis study, the negative predictive value for detection of PCa by MRI was 90% [1]. These and our data indicates that MRI is not able to visualise all csPCa. In 736 patients with a unilateral suspicious lesion on MRI, 145 patients with contralateral PCa-positive SB were identified. 75 of these PCa were clinically significant and treatment-relevant. Especially for patients who are candidates for focal PCa therapy, the exact localisation of the PCa is essential. In this patient subgroup ($n=228$) with an ISUP 1 or 2 PCa in the TB in an unilateral suspicious MRI lesion 56 (25%) showed contralateral PCa-positive SB and 10 (4%) ISUP >2 PCa were missed by the TB. MRI alone would have been misleading for therapy planning in these cases, as focal therapy would not be an appropriate approach. In our study, a relevant proportion of PCa outside the targeted biopsied MRI lesions was found. The additional of 6 SB per patient improves the localisation of PCa.

Conclusions

Needle tracking optimizes the localisation of cancer in the 3D model of the prostate in relation to the MRI suspect lesions. Our results show that the added value of SB with a reduced systematic biopsy scheme is low with regard to prostate cancer detection and PCa risk evaluation. However, there is a relevant added value for localizing multifocal PCa in primary diagnostics by MRI/TRUS fusion biopsy of the prostate.

Limitations

A major limitation of this study is the retrospective setting. The observational character of the current analysis makes the scientific evaluation of the added value of the SB difficult.

Another limitation of our study is that the mpMRI scans were performed at 27 different radiological institutes (1.5 and 3 Tesla MRI scanners) with different levels of experience. This might have led to heterogeneity in the evaluation of mpMRI according to PI-RADS classification. However, our setting reflects real-world practice with different radiological institutes.

In addition, the fact that in the current investigation a reduced number of SB were performed makes a comparison of detection rates of SB and TB with other studies challenging. In the systematic biopsy scheme, the target areas were not re-biopsied. In our opinion, the remaining regions of the prostate were well covered by the median 6 (5–7) additional SB per patient.

The gold standard for the evaluation of a sufficient risk evaluation of a PCa would be the comparison with the histological results of the radical prostatectomy or at least with a template-based saturation biopsy as described in the Promis-study [1]. This comparison is missing in our study.

Acknowledgements There was no sponsorship for the study.

Author contributions KG, JS and SH were responsible for designing and writing the study protocol, inclusion of patients, extracting and analyzing data, interpreting results, statistical analysis, writing and revision of the manuscript. AM, JB, HC, SH and DE were responsible for inclusion of patients, extracting and analysing data, interpreting results and critical revision of the manuscript. EB, HB, and MS were responsible for data analysis and interpretation, critical revision of the manuscript and supervision.

Declarations

Statements and Declaration All authors declare that they have no financial or non-financial conflict of interest regarding this study.

Disclosure The author declare that they have no conflict of interest. Approval of the Ethics Committee (Eth-27/19) for the study was granted by the Berlin Medical Association. All patients have signed an informed consent before study inclusion. A registration no. of the study is not available. Animal studies N/A.

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