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Prostate cancer detection rate in men undergoing transperineal template-guided saturation and targeted prostate biopsy

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Abstract

Objectives: To compare prostate cancer (PCa) detection rate of transperineal template-guided saturation prostate biopsy (SBx) and multiparametric magnetic resonance imaging (mpMRI)/transrectal ultrasound fusion guided targeted biopsy (TBx).

Materials and Methods: We prospectively enrolled 392 men who underwent SBx and TBx in case of suspicious lesions from November 2016 to October 2019. Triggers for a biopsy were an elevated prostate-specific antigen (PSA) and/or positive digital rectal examination and only treatment naïve patients without a previous diagnosis of PCa were included. Study inclusion occurred before biopsy and a prebiopsy mpMRI was available in all men. SBx were taken from 20 different locations according to the modified Barzell zones. The primary endpoint was the detection rate of clinically significant PCa (csPCa) and insignificant PCa (ciPCa) by SBx and/or TBx by comparing the two methods alone and in combination. Additional TBx were taken for any prostate imaging–reporting and data system (PI-RADS) lesion ≥3 seen on the mpMRI. csPCa was defined as any Gleason score ≥7 and ciPCa as Gleason score 6.

Results: A total of 392 men with a median age of 64 years (interquartile range [IQR]: 58–69), a median PSA of 7.0 ng/ml (IQR: 4.8–10.1) were enrolled. Overall, PCa was found in 200 (51%) of all biopsied men, with 158 (79%) being csPCa and 42 (21%) ciPCa. A total of 268 (68%) men with a suspicious mpMRI and underwent a combined TBx and SBx, of whom csPCa was found in 139 (52%). In this subgroup, 116/139 (83%) csPCa would have been detected by TBx alone, and an additional 23 (17%) were found by SBx. Men with a negative mpMRI (PI-RADS < 3, $n = 124$, 32%) were found to have csPCa in 19 (15%) cases. In patients with a negative mpMRI in combination with a PSA density <0.1 ng/ml^2, only 8% (3/36) had csPCa. If only TBx would have been performed and all men with a

negative mpMRI would not have been biopsed, 42/158 (27%) of csPCa would have been missed, and 38/42 (90%) ciPCa would have not been detected. On multivariable analysis, significant predictors of csPCa were increasing PSA (odds ratio, OR: 1.07 [95% confidence interval, CI: 1.03–1.11]), increasing age (OR: 1.07 [95% CI: 1.03–1.11]), PI-RADS score ≥ 3 (OR: 6.49 [95% CI: 3.55–11.89]), and smaller prostate volume (OR: 0.96 [95% CI: 0.95–0.97] ($p < 0.05$ for all parameters).

Conclusion: In comparison to SBx, TBx alone detects csPCa in only ¾ of all men with a positive mpMRI lesion. Thus, systematic biopsies in addition to TBx have to be considered at least in some who undergo a prostate biopsy. In men with a negative mpMRI, SBx still detects 15% csPCa, but similarly overdetecting ciPCa. According to our results, low PSA density and negative mpMRI findings could be used to decide which men can safely avoid biopsy.

KEYWORDS

mpMRI, prostate cancer, transperineal prostate biopsy

1 | INTRODUCTION

Traditionally, suspected prostate cancer (PCa) was diagnosed by a systematic 12-core transrectal ultrasound (TRUS) guided prostate biopsy.[1] Recent development in multiparametric magnetic resonance imaging (mpMRI) of the prostate has challenged this biopsy approach. This approach allows for lesion-directed mpMRI fusion targeted biopsy (TBx) and allows for optimal planning of a biopsy.[1–4] The PRECISION trial showed that a mpMRI directed four targeted core biopsy outperforms a systematic standard 10–12 core transrectal biopsy in detecting clinically significant PCa (csPCa) (38% vs. 26%, $p = 0.005$).[5] In addition, systematic sampling of the prostate is associated with overdetection of clinically insignificant PCa (ciPCa), which is associated with psychological stress, the stigma of a cancer diagnosis, and potential overtreatment of patients.[1,6]

Despite the described advantages of TBx, this approach alone has also shown downsides in other studies by missing a significant number of high-risk cancers.[7–10] The balance of over- and under-detection is challenging and current international guidelines recommend performing a mpMRI before biopsy and to use a combined approach with targeted and systematic biopsies.[11] Whether a TBx alone is sufficient, or if additional systematic biopsies are still needed is an ongoing debate.[11–13] The recently published noninferiority study by Eklund et al.[14] was able to show that MRI with targeted and standard biopsy in men with MRI positive results suggestive of PCa was noninferior to standard biopsy for detecting csPCa in a population-based screening-by-invitation trial and resulted in less detection of ciPCa. However, it is less clear, whether a biopsy can be always omitted when the mpMRI is negative.

While most studies including Eklund et. al.[14] have used a standard TRUS-guided 12-core biopsy or prostatectomy specimen as a reference test which both have their limitations, by either high false-negative PCa rates or a selection bias of men to be treated for PCa, the present study used a template saturation biopsy (SBx) as a reference test with a median of 42 cores. The latter is considered the most accurate diagnostic approach for PCa work-up.[1,15–17]

The aim of the present study is to compare the performance of SBx and TBx in a prospective single-center cohort.

2 | PATIENTS AND METHODS

2.1 | Study design and participants

The present study analyzes the prospectively collected data for prostate biopsy outcomes from the Department of Urology of the University Hospital Zurich, Switzerland. The study is embedded in a large North American and European multicenter study, the Prostate Biopsy Collaborative Group, which was formed in 2009 with the aim to better understand the relationships between prostate biopsy outcomes and established risk factors in heterogeneous cohorts.[18] Here, we report the findings of a separate analysis in which the primary endpoint was the detection rate of csPCa and ciPCa by transperineal SBx and/or TBx by comparing the two methods alone and in combination.

The included patients were referred to the urology department for a PCa workup with a consecutive SBx and dependent on mpMRI findings with or without a TBx. Patients were included in the study prior to biopsy. All men had a mpMRI of the prostate prior to biopsy. The recommendation for a biopsy was based on prostate-specific antigen (PSA), digital rectal examination (DRE) findings, life expectancy, morbidity, and available risk calculators. MRI findings were not used as a decision aid if a man should undergo a biopsy during the time of the study. Men with a prior diagnosis of PCa, severe disease (e.g., dementia, severe cardiovascular disease), or a contraindication to MRI were not included in the study. Other exclusion criteria were

patients who had undergone transrectal confirmatory biopsy because of strong suspicion of locally advanced disease or patients who had not provided informed consent.

All men received a mpMRI followed by a transperineal SBx. In case of a suspicious MRI lesion, additional TBx were performed. The study was reviewed and approved by the local ethics committee (KEK Nr. 2016-00075). All participants of the study provided written informed consent.

The mpMRI was performed in a 3-T MAGNETOM Skyra MRI system (Siemens) with T2-weighted, diffusion-weighted, and dynamic contrast-enhanced sequences. All mpMRI examinations were evaluated by board-certified radiologists in accordance with the current guidelines of prostate MRI reading and all scans were reported using the prostate imaging–reporting and data system (PI-RADS) Score.[4] The prostate volume was inferred by the MRI with the formula height × length × width and is indicated in milliliters (ml).

2.2 | Biopsy and histopathology

All prostate biopsies were performed as outpatient procedures under general anesthesia in the lithotomy position. The BiopSee® MRI/TRUS fusion biopsy system (Medcom) was used for planning and conducting the biopsy.[19] It includes computer software (BiopSee® 2.0) for image fusion with a biplanar TRUS probe. One to three SBx were normally taken from each of the 20 modified Barzell zones[20] and additional TBx were taken in case of any lesion found on mpMRI (2–3 biopsy cores per lesion). Each collected biopsy core was evaluated separately by a specialized uropathologist and in the case of PCa, diagnosis, and grade were confirmed by a second board-certified pathologist. CsPCa was defined as ≥Gleason score of 3 + 4 = 7a, and a ciPCa insignificant carcinoma as Gleason score 3 + 3 = 6.

2.3 | Secondary outcome measures

Besides the detection rate of PCa in SBx and TBx, the following secondary outcomes were analyzed: Stratification of the csPCa detection rate by mpMRI PI-RADS score and PSA density (total PSA divided by prostate volume), as well as identification of clinical predictors of biopsy outcome.

2.4 | Statistical analysis

The clinical, radiological, and histological data were evaluated using descriptive statistics. Data entry and evaluation were performed using SPSS version 26.0 (IBM Corp). Continuous variables were presented as a median and interquartile range (IQR), and categorical variables as numbers with percentages. To compare the proportions of csPCa and ciPCa in SBx and TBx, McNemar's test was used. Multivariable logistic regression analysis was modeled to evaluate predictors of csPCa with age, prostate volume, PSA, PSA density, and PI-RADS scores of 3, 4, or 5 as covariates with all data collected prospectively. To estimate the goodness of fit a Hosmer and Lemeshow test was used. For the percentage of variance, the Nagelkerke R^2 value was estimated. All tests were two-sided with $p < 0.05$ considered statistically significant.

3 | RESULTS

A total of 1017 biopsies were performed at our institution during the study time period November 2016 to October 2019. A relevant amount of these biopsies ($n = 553$) were conducted as a part of an active surveillance protocol, that is, they had an already known PCa (Figure 1). A total of 464 men were not yet diagnosed with PCa and received a prostate biopsy for further evaluation. Of these 464 patients, 50 received only a 6–12-core TRUS biopsy under local anesthesia. These patients were mostly older, with comorbidities and suspected advanced high-grade PCa, and only needed a biopsy for histopathological confirmation of advanced PCa. The remaining 414 patients fulfilled the study criteria and received a mpMRI fusion-guided transperineal template SBx with/without TBxs. A total of 22 men (2%) refused to participate or were not included due to staffing shortage. A total of 392 men were included and available for the final analysis of this study.

Patient characteristics are shown in Table 1. The median age was 64 years (IQR: 58–69) and the median PSA was 7 ng/ml (IQR: 4.8–10.1). The median prostate volume was 43 cm^3 (IQR: 36–66). A previous negative biopsy was reported in 115/392 (29%) men and 79/392 (20%) had a positive family history for PCa. A total of 268/392 (68%) showed suspicious mpMRI lesions with either a PI-RADS 3 ($n = 87$), a PI-RADS 4 ($n = 123$), or a PI-RADS 5 lesion ($n = 58$), whereas 88 patients showed more than one ≥PI-RADS 3 lesion. The median number of biopsy cores taken was 42.

3.1 | Overall PCa detection rate

Overall PCa detection rate of all biopsy patients with SBx in combination with TBx was 51% (200 out of 392 performed biopsies), whereas the detection rate for csPCa was 40% (158/392) and 11% (42/392) for ciPCa (Figure 2 and Table 2). A total of 124 (32%) men had a nonsuspicious mpMRI (PI-RADS < 3 lesions) and underwent SBx without additional TBx.

3.2 | Biopsy results for men with a positive mpMRI

Men with a positive mpMRI PI-RADS ≥ 3 ($n = 268$, 68%) all underwent SBx with additional TBx. A total of 116/268 (43%) were diagnosed with csPCa by TBx alone, whereas the number of csPCa increased to 139/268 (52%) when SBx was additionally accounted. Thus, a TBx alone would have missed 9% (23/268) of men with

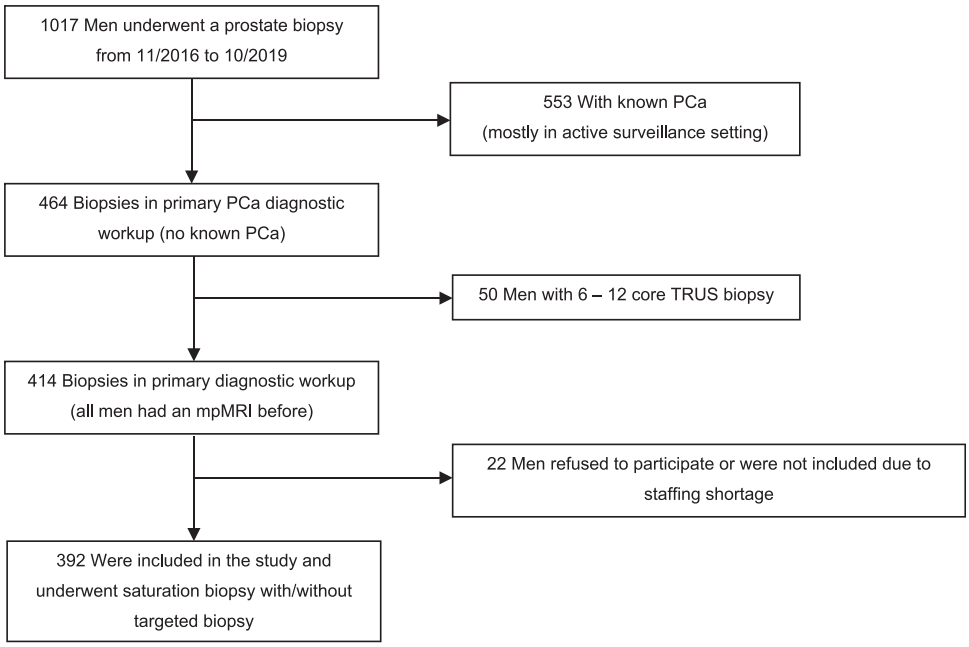

FIGURE 1 Flowchart for patient selection. mpMRI, multiparametric magnetic resonance imaging; PCa, prostate cancer; TRUS, transrectal ultrasound

suspicious lesions on mpMRI. All csPCa detected by TBx were also detected by SBx, and, therefore, no additional csPCa was found by TBx alone resulting in the same detection rate of 52% in SBx alone and the combined approach. Detection rates of csPCa were significantly associated with increasing PI-RADS score (Figure 3 and Table 3).

In men with PI-RADS 3 lesions ($n = 87$), TBx alone identified 13 (57%) of 23 csPCa found in SBx. The TBx detection rate increased in PI-RADS 4 ($n = 123$) and 5 ($n = 58$) lesions to 58/79 (83%) and 45/46 (98%) respectively ($p < 0.05$) (Figure 3).

Contrary, ciPCa was found in 4 out of 87 (5%) men with PI-RADS 3 lesion, while in PI-RADS lesions 4 and 5 ciPCa was detected in 3/123 (2%) and 2/58 (3%), respectively. CiPCa was found in 10/268 (4%) by TBx alone and in 17/268 (6%) by SBx or SBx+TBx, respectively. Of note, six patients were classified as ciPCa by TBx, but identified as csPCa by SBx.

3.3 | Biopsy results for men with a negative mpMRI

Men with a negative mpMRI ($n = 124$, 32%) showed in 19/124 (15%) cases a csPCa, as compared to 139/268 (52%) cases with mpMRI lesions. CiPCa was found in 25/124 (20%) men with a negative mpMRI.

If only TBx had been performed in men with a positive mpMRI and all men with a negative mpMRI would not have been biopsied at all, 42/158 (27%) csPCa would have been missed, whereas on the other hand, 38/42 (90%) ciPCa would not have been diagnosed.

3.4 | Predictors for a csPCa

Multivariable analysis identified increasing PSA (odds ratio, OR: 1.07 [95% confidence interval, CI: 1.03–1.11]), increasing age (OR: 1.07 [95% CI: 1.03–1.11]) and PI-RADS score ≥ 3 (OR: 6.49 [95% CI: 3.55–11.89]) and smaller prostate volume (OR: 0.96 [95% CI: 0.95–0.97]) as independent predictors of csPCa (for all $p < 0.05$).

Stratification by four different PSA density cut-off values (0.07, 0.1, 0.15, and 0.2 ng/ml^2) was carried out. These cutoff values have already been evaluated by other study groups and were thus applied here.[21–24] PSA density with a cutoff at 0.1 ng/ml^2 showed a significant association with the detection rate of csPCa (OR: 37 [95% CI: 4.12–334.06]; $p < 0.05$). Among men with PSA density < 0.1 ng/ml^2, the risk of being diagnosed with csPCa was 22% (95% CI: 14–31). A PSA density between 0.15 and 0.19 showed a csPCa risk of 43% (95% CI: 31–55) and a PSA density of >0.2 ng/ml^2 was found to have a csPCa risk of 65% (95% CI: 56–74) ($p < 0.05$) (Figure S1 and Table S1). Men with a negative mpMRI did not only less likely to harbor csPCa, but were also more likely to have a lower PSA density value. Men with a negative mpMRI and a PSA density < 0.1 ng/ml^2 ($n = 36$, 9% of all men) did not harbor csPCA in 92% (33/36).

4 | DISCUSSION

In this biopsy outcome study, we analyzed the detection rate of csPCa and performance of TBx in comparison to SBx in 392 men who underwent a mpMRI fusion TBx and SBx. We found an overall csPCa detection rate of 40%. In men with positive mpMRI, 52% were found to harbor csPCa. In this subgroup, TBx strategy alone would have

TABLE 1 Patient characteristics and PI-RADS assessment categories

Characteristic	*n* = 392
Age at biopsy, median, y	64.0 (56.6–71.4)
PSA level (ng/ml), median (IQR)	6.7 (4.8–10.1)
PSA density (ng/ml^2), median (IQR)	0.14 (0.09–0.21)
Prostate volume, median (IQR), cm^3	43.1 (36–66.6)
Family history of prostate cancer	
Positive	79 (20)
Negative	313 (80)
DRE	
Positive	61 (16)
Negative	304 (77)
n/a	27 (7)
Number of cores, median (IQR)	42 (38–45)
Number of targeted cores, median (IQR)	5 (0–8)
Prior negative biopsy	
Yes	115 (29)
No	277 (71)
Number of past negative biopsies, median (IQR)	1 (1–2)
MpMRI positive	268 (68)
PI-RADS 3	87 (22)
PI-RADS 4	123 (31)
PI-RADS 5	58 (15)
No significant lesion on mpMRI	124 (32)

Note: Data are presented as numbers (percent).

The prostate volume was measured on mpMRI.

Abbreviations: DRE, digital rectal examination; IQR, interquartile range; mpMRI, multiparametric magnetic resonance tomography; PI-RADS, prostate imaging–reporting and data system; PSA, prostate-specific antigen; y, year.

found 83% of all csPCa. Only 15% of all patients with a negative mpMRI showed csPCa. In this group, a prostate biopsy could have been avoided in many cases, especially when PSA density was additionally low.

Our study showed a csPCa detection rate by TBx alone of 43% with an increase of 9% when additional SBx was performed. Filson et al.[25] showed a detection rate by TBx of 27.8% (229/825) and an increase by 7.3% (60/825) with an additional 12-core SBx. Oderda et al.[26] reported an improvement by 9% with 10–14 core SBx, while Rouvière et al.[7] could not show a significant difference between SBx and TBx (29.9% vs. 32.3%, respectively). All of the abovementioned studies performed the biopsies through a transrectal approach, with comparatively less biopsy cores than in the present study. To our knowledge, only two other studies investigated PCa detection rates of TBx in comparison with a transperineal approach. Our center previously reported initial SBx results.[15] At that time, median biopsy cores of 40 per patient were taken and a csPCa detection rate by TBx alone of 44.3% (129/291) was reported, which is similar to our study. However, almost a 20% increase of csPCa detection through additional SBx was found, which was distinctly higher compared to this study (9%). In contrast, Miah et al.[27] showed a csPCa rate by TBx alone of 41.1% (263/640) and only three men (0.8%) had csPCa exclusively in non-TBx cores. The differences in these results might depend on the number of cores taken (16 vs. 40), or the type of systematic biopsy protocol. In addition, the experience of radiologists in assessing mpMRI and urologists in performing TBx biopsy, PI-RADS classification, and standardization might be other reasons for the discrepancies of the results.

In the randomized study of Ahmed (PROMIS) et al.[1] MRI fusion TBx improved the accuracy to detect csPCa in men presenting with elevated PSA or suspected DRE, compared to the standard TRUS biopsy approach. However, patients did not undergo additional systematic biopsy sampling of the prostate in the study from Ahmed et al.[1] Thus, no conclusions can be drawn from this study if avoidance of any systematic sampling in men with positive mpMRI is reasonable. In contrast, the recent work of Ahdoot et al.[28] revealed that a combined biopsy approach (12-core systematic biopsy in combination with TBx) in men with an MRI lesion resulted in a higher detection rate of csPCa, compared to TBx alone. In addition, TBx alone underestimated the Gleason grade of some tumors when compared to the combined approach. Of interest, Ahdoot et al.[28] also reported a Gleason score upgrade of 30.9% in the TBx group when compared to final pathology after radical prostatectomy. When systematic biopsies were also considered, this value dropped to 14.4%. These findings are in line with our results since a Gleason score upgrade was found in 35% when TBx alone was considered, as compared to only 7% with a combined approach of SBx with TBx.

In our study, systemic biopsies were performed as SBx, with up to 42 cores for maximum coverage of the prostate. This methodology has the potential to provide a most possible precise comparison of the diagnostic accuracy of both the TBx and mpMRI. Compared to data from Ahdoot et al.[28], the present study allows a more detailed description of the diagnostic accuracy of TBx, especially concerning men who would not undergo radical prostatectomy.

Both mentioned studies above used the mpMRI as a triage test, and men with a negative mpMRI did not undergo a systematic prostate biopsy. It is still a matter of debate if all men with elevated PSA levels or/and suspicious DRE but a negative mpMRI can safely undergo surveillance without any biopsy.[12,29] In general, an abnormal DRE is a strong predictor for csPCa. Schröder et al.[30] showed that 40%–50% of all palpable abnormalities found on DRE turned out to be malignant.[30] Thus, men with an abnormal DRE should most likely undergo a biopsy even when imaging does not show any target. In our center, men with negative mpMRI (*n* = 124) who underwent SBx, 19 (15%) still had csPCa. This number is in line with the current literature and confirms that >80% of men with a negative mpMRI do not harbor csPCa.[31] According to our results, a viable option to avoid safely many biopsies in men with a negative mpMRI is the use of PSA

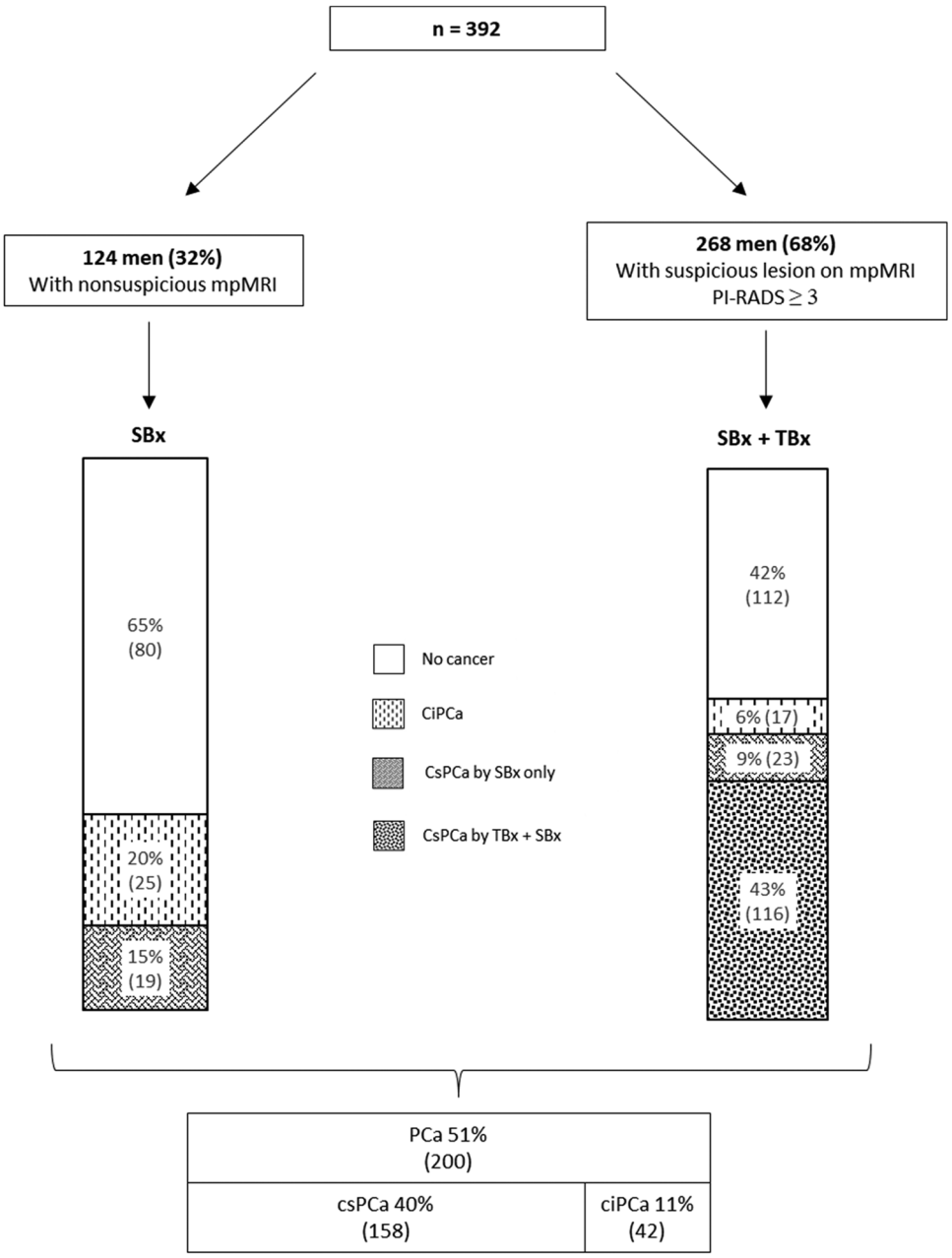

FIGURE 2 Prostate cancer detection rates. Prostate cancer detection rates in men with a lesion on mpMRI and in men without any lesion. ciPCa, clinically insignificant PCa; csPCa, clinically significant PCa; mpMRI, multiparametric magnetic resonance imaging; PCa, prostate cancer; PI-RADS, prostate imaging–reporting and data system; SBx, saturation biopsy; TBx, targeted biopsy

TABLE 2 Prostate cancer detection rates according to different biopsy strategies

	Biopsy strategy			
	SBx (*n* = 392), *n* (%)	TBx (*n* = 268), *n* (%)	SBx in combination with TBx (*n* = 268), *n* (%)	*p* (SBx vs. TBx + SBx)
PCa	200/392 (51)	126/268 (47)	156/268 (58)	<0.0001
csPCa	158/392 (40.3)	116/268 (43.3)	139/268 (52)	<0.0001
ciPCa	42/392 (10.7)	10/268 (3.7)	17/268 (6.3)	0.167
No PCa	192/392 (49)	144/268 (53.7)	112/268 (42)	

Note: Data are presented as numbers (percent).

TBx and SBx + TBx were only performed when at least one suspicious lesion on mpMRI (as defined by PI-RADS ≥ 3 lesions) was seen.

p-values were calculated with McNemar's test.

Abbreviations: ciPCa, clinically insignificant PCa; csPCa, clinically significant PCa; mpMRI, multiparametric magnetic resonance imaging; PCa, prostate cancer; PI-RADS, prostate imaging–reporting and data system; SBx, saturation biopsy; TBx, targeted biopsy.

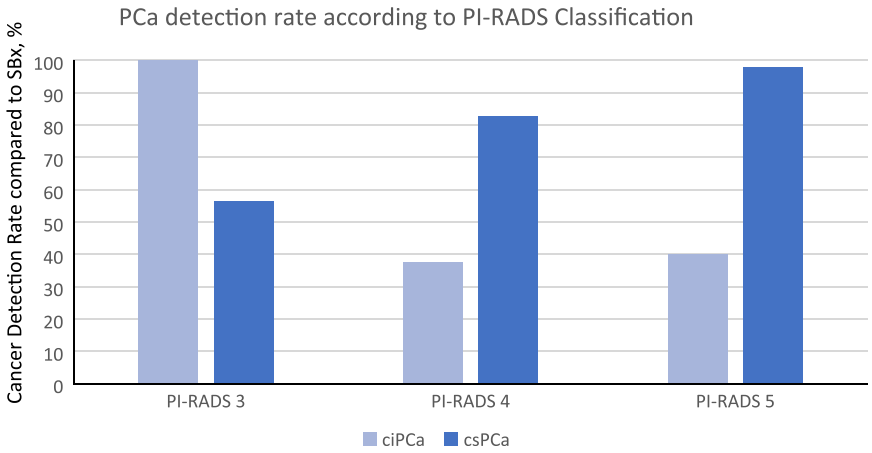

FIGURE 3 Cancer detection rate by TBx in men with positive mpMRI and according to PI-RADS classification. Prostate cancer detection rates in TBx according to the PI-RADS scores 3–5. SBx detection rates serve as the reference test. ciPCa, clinically insignificant PCa; csPCa, clinically significant PCa; mpMRI, multiparametric magnetic resonance imaging; PCa, prostate cancer; PI-RADS, prostate imaging–reporting and data system; SBx, saturation biopsy; TBx, targeted biopsy [Color figure can be viewed at wileyonlinelibrary.com]

density. Our data shows that men with a negative mpMRI and a low PSA density < 0.1 ng/ml^2 (9% of all men) almost all had a negative SBx (92%), and thus could safely be spared from a prostate biopsy.

In men with mpMRI positive lesions, the TBx detection rate might depend on various factors, such as the experience of the radiologist, the biopsy systems, and/or the fusion techniques, or the number of cores taken. In our study, the PI-RADS score of the mpMRI was associated with csPCa found on biopsy. TBx alone found csPCa in 98% of PI-RADS 5 lesions and in 83% of PI-RADS 4 lesions, respectively. Only 57% of TBx performed for PI-RADS 3 lesions were positive for csPCa. TBx missed 43% (10/23) of csPCa's in PI-RADS 3 lesions when compared to SBx. This demonstrates that TBx alone is a suboptimal biopsy approach for men harboring PI-RADS 3 lesions, but on the other hand, systematic biopsies might be limited in men presenting with PI-RADS 4 or especially PI-RADS 5 lesions.[9,15,28]

Even though SBx is considered the most precise whole gland biopsy work-up, the main issue remains overdetection of ciPCa and the potentially increased associated morbidity in comparison with a limited systematic biopsy. It might lead to a higher rate of urinary retention with the need for temporary catheterization, infection, hematuria, or haematospermia.[32] Nevertheless, data regarding increased morbidity when more biopsy cores are taken are scarce.

The strength of this study is SBx has been used as a reference test, which is more accurate than 12-core TRUS guided biopsy. This allows us to draw stronger conclusions for the interpretation of mpMRI results and the TBx approach and can additionally help to adapt future state-of-the-art biopsy protocols.

The limitations include an interobserver variety of mpMRI assessment by different radiologists and discrepancies in the delineation of the lesions after fusion with the TRUS by different urologists with varying professional experience.

TABLE 3 Cancer detection rate according to PI-RADS classification

PI-RADS score and csPCa by biopsy method	*n*	Detection rate (%) according to biopsy method and overall PPV	OR of csPCa detection rate given PI-RADS score ≥ 3 compared to negative mpMRI
PI-RADS 3	87		OR: 2.28 (95% CI: 1.08–4.79); $p < 0.05$)
TBx csPCa	13	57%	
SBx csPCa	23	100%	
Overall csPCa (SBx + TBx)	23	PPV 26.4	
PI-RADS 4	123		OR: 8.51 (95% CI: 4.34–16.65); $p < 0.05$)
TBx csPCa	58	83%	
SBx csPCa	70	100%	
Overall csPCa (SBx + TBx)	70	PPV 56.9	
PI-RADS 5	58		OR: 21.04 (95% CI: 8.43–52.46); $p < 0.05$)
TBx csPCa	46	98%	
SBx csPCa	45	100%	
Overall csPCa (SBx + TBx)	46	PPV 79.3	
Overall PI-RADS ≥ 3	268		OR: 6.49 (95% CI: 3.55–11.89); $p < 0.05$)
TBx csPCa	139	83.5%	
SBx csPCa	116	100%	
Overall csPCa (SBx + TBx)	139	PPV 51.9	

Odds ratios were calculated of csPCa detection rate given PI-RADS score ≥ 3 compared to negative mpMRI (PI-RADS score ≤ 2).

Abbreviations: CI, confidence interval; csPCa, clinically significant PCa; mpMRI, multiparametric magnetic resonance imaging; OR, odds ratio; PCa, prostate cancer; PI-RADS, prostate imaging–reporting and data system; PPV, positive predictive value; SBx, saturation biopsy; TBx, targeted biopsy.

5 | CONCLUSION

TBx alone is diagnostic for csPCa in about ¾ of all men with a positive lesion on mpMRI. Our study suggests, that some kind of systematic biopsies in addition to TBx are to be considered in men with PIRADS 3 lesion and might be avoided in men with PIRADS 4 or 5 lesion. In men with a negative mpMRI, SBx still detects 15% csPCa, but simultaneously overdetecting a relevant amount of ciPCa. PSA density could be used in this group to decide which men can safely avoid biopsy.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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