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ARTICLE

Impact of biparametric prebiopsy prostate magnetic resonance imaging on the diagnostics of clinically significant prostate cancer in biopsy naïve men

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ABSTRACT

Background: The objective of this study was to compare the prevalence of clinically significant prostate cancer (CSPCa) in men with biparametric prebiopsy prostate magnetic resonance imaging (MRI) and lesion-targeted biopsies (TBs) to the group of men without prebiopsy MRI in an initial biopsy session.

Methods: The MRI group consists of men enrolled into four prospective clinical trials investigating a biparametric MRI (bpMRI) and TB while the non-MRI group was a retrospective cohort of men collected from an era prior to a clinical use of a prostate MRI. All men had standard biopsies (SBs). In the MRI group, men had additional TBs from potential cancer-suspicious lesions. CSPCa was defined as Gleason score $\geq 3+4$ in any biopsy core taken. All the patients were prostate biopsy naïve.

Results: The MRI group consists of 507 while the non-MRI group 379 men. Mean age and prostate specific antigen (PSA) level differed significantly ($p < 0.05$) between the groups: In the MRI group, 64 years and 7.6 ng/ml, respectively, and in the non-MRI group 68 years and 8.2 ng/ml, respectively. Significantly ($p < 0.05$) more CSPCa was diagnosed with initial biopsies in the MRI group (48%) compared to non-MRI group (34%). In men with no CSPCa diagnosed during the initial biopsies, significantly fewer ($p < 0.05$) men had upgrading re-biopsies in the MRI group (5%) than in the non-MRI group (19%) during the follow up.

Conclusions: Prebiopsy bpMRI with TBs combined with SBs could lead to earlier diagnoses of CSPCa compared with men without prebiopsy prostate MRI used in initial PCa diagnostics.

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Introduction

Although, prostate cancer (PCa) had generally a good prognosis, it covers a wide spectrum of diseases, including cancers with highly malignant potential [1]. Thus, histological grade of a PCa is the most substantial factor for choice of treatment and further prognosis [1–3]. Therefore, correct histological diagnosis of clinically significant PCa (CSPCa) should ideally be achieved with initial biopsies.

When there is a clinical suspicion of a PCa, which is commonly based on elevating prostate-specific antigen (PSA) level or an abnormal finding in digital rectal examination (DRE), primary diagnostic protocol has formerly been based on 10–12 biopsy cores taken under ultrasound guidance from standard locations of prostate gland (standard biopsies, [SBs]). However, the low sensitivity of SBs for CSPCa has been shown in multiple previous studies [4,5]. Therefore, after negative SBs and a rising PSA level, re-biopsies should be considered. Remaining suspicion of a PCa with repeated biopsies is not only unpleasant for a patient, but the biopsies also include a risk of major complications, even if the risk with a modern antibiotic prophylaxis might be low [6–8]. Due to a high prevalence of PCa, this is also a burden to the healthcare system. Additionally, diagnostic delay gives time for progression to a non-diagnosed CSPCa. Thus, there is an evident need for an improved diagnostic protocol of PCa, enabling early correct histological diagnosis following suspicion of PCa.

Prebiopsy prostate magnetic resonance imaging (MRI) is increasingly being used in men with a clinical suspicion of PCa. Prebiopsy prostate MRI with targeted biopsies (TBs) based on MRI report was shown to increase sensitivity in CSPCa diagnostics [4,9–13]. Until 2019, prebiopsy MRI was recommended mainly for men with cancer-negative biopsies and a clinical suspicion of CSPCa, however, the most recent guideline of European Association of Urology (EAU), recommends the use of prebiopsy multiparametric MRI to all biopsy naïve patients as well [3].

Object of the study was to compare a prevalence of CSPCa in initial biopsies in men having prebiopsy

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biparametric prostate MRI (bpMRI) with TBs to men having PCa diagnostics performed with the traditional diagnostic protocol, without prebiopsy MRI. As a secondary outcome, we compared an initial biopsy result to a prostatectomy specimen and a delay to diagnosis of CSPCa between the study groups during a follow-up period.

Materials and methods

Study groups consist of two cohorts: a prospectively collected patient cohort having bpMRI (MRI group) and a retrospectively collected control cohort without MRI (non-MRI group) used in an initial biopsy session. Inclusion criteria in the study were a suspicion of a PCa which was usually derived from an abnormal finding in DRE or an elevated PSA level. Men with a PSA level over 20 ng/ml prior biopsies, a prior prostate MRI taken or a prior PCa diagnosis, were excluded. Histopathological results were reported using Gleason grade groups (GGG) according to the classification of the 2014 International Society of Urological Pathology (ISUP) Gleason Grading Conference of Prostatic Carcinoma [14]. In the analysis, GGG $\geq$ 2 (Gleason score $\geq 3+4$) was defined as CSPCa and GGG = 1 (Gleason score = $3+3$) as non-significant PCa. In patient level, a Gleason score and thus also a GGG was assigned by using the highest Gleason score reported in any biopsy core taken (standard or targeted). All the study biopsies were taken *via* transrectal approach and the prostate volumes were estimated using transrectal ultrasound (TRUS).

MRI group

The MRI group consists of men from three consecutive, prospective and registered prebiopsy prostate MRI trials (IMPROD NCT01864135, IMPROD 2.0 NCT02844829 and PROMANEG NCT02388126) and one multicenter study (Multi-IMPROD NCT02241122). All the study biopsies were taken during 4/2013–9/2017.

In all the studies, prebiopsy, biparametric 3T prostate MRI-scan were performed using a surface coil with exception of one center where 1.5T MRI-scanner was used (89 included patients). An unique IMPROD bpMRI protocol was used, consisting T2-weighted acquisition and three separate DWI acquisitions. All imaging data sets were reported by a local radiologist, using a five-step tiered IMPROD bpMRI Likert scoring system and confirmed centrally by one designated central reader to guarantee reporting integrity before each biopsy procedure. The central reader was unaware of clinical data. All data about the MRI protocols and the reporting system are freely available at the following address: http://petiv.utu.fi/improd/.

Depending on a prostate volume, 10–12 systematic biopsy cores were taken from all the patients. Additionally, if cancer-suspicious lesion (IMPROD Likert score $\geq$ 3) were present, two TB cores per lesion were taken. In IMPROD trial, only a dominant lesion was targeted, whereas in Multi-IMPROD, IMPROD 2.0 and PROMANEG trials, two of the most dominant lesions were targeted. A cognitive targeting method was used, in exception of one center, where a MRI-TRUS fusion was used ($n = 45$).

non-MRI group (control cohort)

The control cohort was retrospectively collected. It consists of men having initial prostate biopsies taken prior to a clinical utility of a prostate MRI in our center. The patient recruitment was performed by an automatic search from a patient registry using a pathologic laboratory sample code for prostate biopsies. Inclusion criteria in the search algorithm were first biopsies in our center and a prebiopsy PSA level under 20 ng/ml. A period when the study biopsies were taken restricted to 1/2011–3/2013, aiming to preserve similarity between the study cohorts.

Statistical analysis

In all the analysis, significance of differences between the study groups was calculated using a Pearson's chi-square method for nominal variables and with independent samples T-test for continuous variables. A level of significance was set to 0.05. Delay to CSPCa diagnosis during the follow-up was represented using a Kaplan–Meier graph, restricting it to the data of first 2 years due a significant difference in length of follow-up periods between the study groups. All the statistical analyses were made with SPSS version 24 for Windows (IBM Corp., Armonk, NY).

Ethics

All the included studies were conducted in compliance with the current revision of Declaration of Helsinki guiding physicians and medical research involving human subjects (59th World Medical Association General Assembly, Seoul, Korea, 2008). Prior to commencement of each of the studies, the study protocol, the patient information sheet and the informed consent form were approved by the local ethics committee. Each enrolled man gave written informed consent prior the included studies.

Results

Baseline characteristics of the study groups are represented in Table 1 and a flowchart of the patient inclusion is represented in Figure 1. The MRI group consists of 507 men and the non-MRI group 379 men. There was a significant ($p < 0.05$) difference in a mean age and a mean PSA level between the study groups. The mean age and the mean PSA were in the MRI group 64 years and 7.6 ng/ml, respectively, and in the non-MRI group 68 years and 8.2 ng/ml, respectively. Mean prostate volumes were in the MRI group and in the non-MRI group 43 and 44 ml, respectively, and the difference was not significant. Due to the study setting, mean follow-up times differ substantially between the study groups, 736 d in MRI group and 2381 d in non-MRI group ($p < 0.05$).

The results of initial biopsies are represented in Table 2. CSPCa (GGG 2–5) were diagnosed with initial biopsies in 48%

Table 1. Baseline characteristics of the study patients.

	Non-MRI group	MRI group	*p* Value
n	379	507	
Mean age years (range)	68 (39–91)	64 (29–82)	<0.001
Mean PSA ng/ml (range)	8.2 (0.42–19)	7.6 (1.220)	0.020
Mean prostate volume ml (range)	44 (16–120)	43 (14–50)	0.245
Mean follow-up time, days (range)	2381 (1941–2758)	736 (36–1596)	<0.001

MRI: biparametric prebiopsy magnetic resonance imaging; PSA: prostate specific antigen.

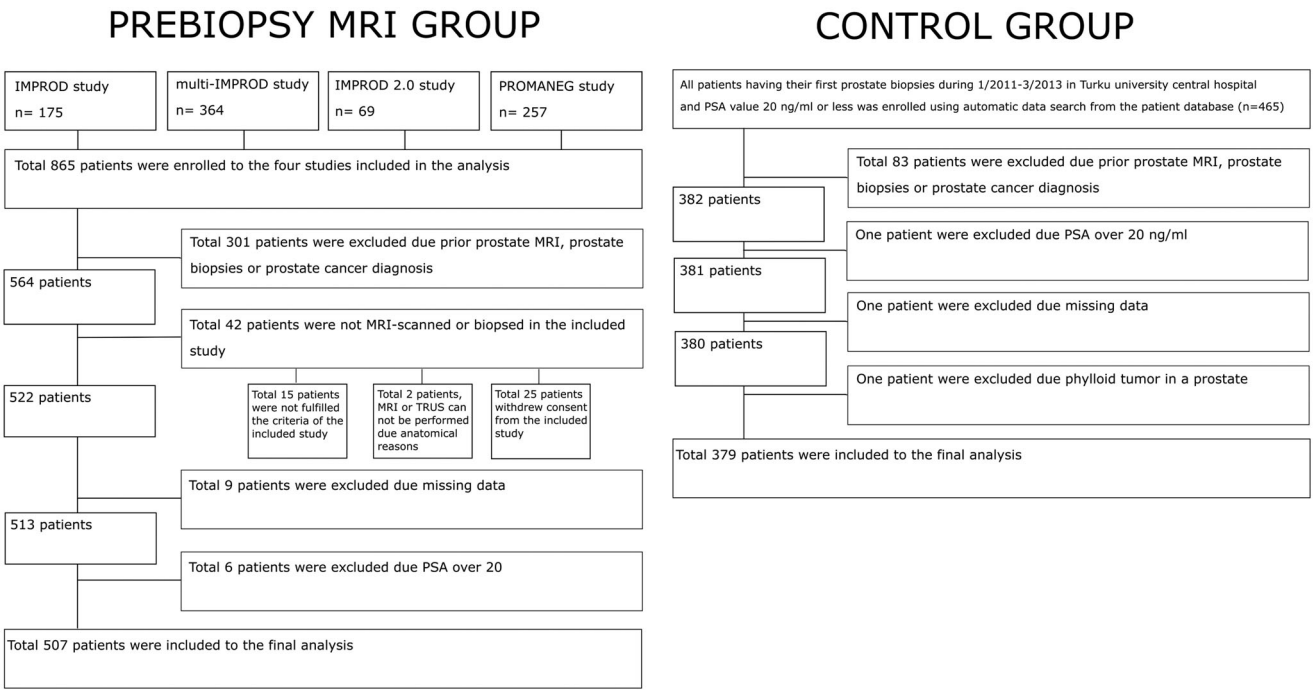

Figure 1. A flowchart of the study patient inclusion.

Table 2. Histological diagnosis in initial biopsies divided to the Gleason grade groups according to The International Society of Urological Pathology Gleason Grading Conference of Prostatic Carcinoma (2014).

	Non-MRI group	MRI group	*p* Value
n	379	507	
Benign (%)	190 (50)	179 (35)	<0.001
Any PCa (%)	189 (50)	328 (65)	<0.001
Gleason grade group 2–5 PCa (%)	130 (34)	245 (48)	<0.001
Gleson grade group 1 (%)	59 (16)	83 (16)	0.747
Gleson grade group 2 (%)	50 (13)	89 (18)	0.077
Gleson grade group 3 (%)	17 (5)	57 (11)	<0.001
Gleson grade group 4 (%)	20 (5)	52 (10)	0.007
Gleson grade group 5 (%)	43 (11)	47 (9)	0.312

MRI: biparametric prebiopsy magnetic resonance imaging; PCa: prostate carcinoma.

of men in the MRI group and in 34% of men in the non-MRI group ($p < 0.001$). The rate of non-clinically significant PCa (GGG 1) was 16% in both study groups. When all the biopsy results divided into the GGGs, significantly ($p < 0.05$) higher rates of GGG 3 and GGG 4 graded PCas were discovered in the MRI group.

Upgraded biopsy results during the follow-up are presented in Table 3. In men with a benign or a GGG 1 histology in initial biopsies, upgrading histology in re-biopsies was in 5% of men in the MRI group and in 19% of men in the non-MRI group ($p = 0.001$). In addition, histology of the initial biopsies upgraded to a highly aggressive (GGG $\geq$ 3) PCa in re-biopsies in 1% and 11% PCa of the men in the MRI group and the non-MRI group ($p < 0.001$), respectively. We made an additional analysis to the non-MRI group dividing it to men having MRI and men without having MRI during the follow-up. Substantially more CSPCa and also more aggressive PCas were found in men having MRI during the follow-up.

Histological findings of prostatectomy specimen compared to the initial biopsy results are represented in Table 4. Upgrading histology in prostatectomy specimen was substantially and significantly ($p = 0.002$) more common in the non-MRI group (57%) than in the MRI group (36%), and capsule invasive PCa was significantly more common in the non-MRI group.

A diagnostic delay and a number of biopsy sets taken for the diagnosis of CSPCa are represented in Figures 2 and 3. In Figure 2, a Kaplain–Meier graph of first 2 years of the follow-up indicates a trend that more CSPCa diagnosed during the follow-up in the non-MRI group in comparison to the MRI group. The same trend is seen in Figure 3, which represents how many biopsy sets had to be taken for the diagnosis of CSPCa.

Discussion

In this study, we compared in a non-randomized setting, a prospectively collected patient group having a prebiopsy

Table 3. Biopsy findings during the follow-up.

				Non-MRI group		
n	MRI group	Non-MRI group	*p* Value	MRI before re-biopsies subgroup	No MRI before re-biopsies subgroup	*p* Value
	379	507		23	226	
Benign or GGG 1 (%) in primary biopsies	262 (69)	249 (49)	<0.001	23 (100)	226 (100)	
GGG ≥ 2 PCa in rebiopsies if primary biopsies benign or GGG 1 (%)	13 (5)	47 (19)	0.001	12 (52)	35 (25)	<0.001
GGG ≥ 3 PCa in rebiopsies if primary biopsies benign or GGG 1 (%)	3 (1)	27 (11)	<0.001	6 (26)	21 (9)	0.014

GGG: Gleason grade group according to the International Society of Urological Pathology Gleason Grading Conference of Prostatic Carcinoma (2014), MRI: biparametric prebiopsy magnetic resonance imaging; PCa: prostate carcinoma.

Table 4. Prostatectomy findings during the follow-up.

	MRI group	Non-MRI group	*p* Value
n	379	507	
Prostatectomy (% of patients in the cohort)	173 (46)	77 (20)	<0.001
Upgrading Gleason grade in prostatectomy specimen (% of prostatectomies in the cohort)	62 (36)	44 (57)	0.002
pT3-pT4 in prostatectomy specimen (% of prostatectomies in the cohort)	71 (41)	43 (56)	0.030

GGG: Gleason grade group according to the International Society of Urological Pathology Gleason Grading Conference of Prostatic Carcinoma (2014); MRI: biparametric prebiopsy magnetic resonance imaging; PCa: prostate carcinoma.

bpMRI with TBs used in an initial PCa diagnostics (MRI group) to a retrospectively collected control cohort in whom initial PCa diagnostics were made in an era, when there was no prostate MRI in clinical use in our center (non-MRI group). All the patients were having biopsies due to suspicion of PCa and were prostate biopsy naïve. The study cohorts vary significantly in mean age, mean PSA level and follow up time. Taking this into account, we represented a quite clear and significant ($p < 0.05$) difference in the rate of CSPCa in initial biopsies between the study groups: 48% in the MRI group and 34% in the non-MRI group. In addition, significantly more patients got a CSPCa diagnosed during the follow-up and an upgrading PCa histology in a prostatectomy specimen in the non-MRI group. Because of the variability between the study groups baseline characteristics and follow-up time, in addition to non-randomized study setting and retrospective collection of the control cohort, this study should be considered more as a descriptive study and, therefore, far-reaching conclusions should not be done. Also, it should be noted, that we did not analyze separately men with cognitive or MRI-TRUS fusion guidance in targeting suspicious lesions in the MRI group, because recent studies showed no significant difference between various methods of MRI TB for CSPCa detection [15,16].

The results of our study were as expected in a light of prior studies. In the MRI group, there were more CSPCas diagnosed in the initial biopsies. However, due to the study design, where a combination of standard and TB in the MRI group was performed, there was no difference in the rate of non-significant PCa between the study groups. In an analysis of the follow-up period, there should be very careful with conclusions due to the significantly longer follow-up and the higher mean age of the men in the non-MRI group. However, there was a trend, in which more CSPCas diagnosed with the initial biopsies in the MRI group, and more with re-biopsies in the non-MRI group. Also highly aggressive (GGG ≥ 3) PCas missed substantially more often with the initial biopsies in the non-MRI group.

Many patients from the non-MRI group had a MRI performed during the follow-up and in that subgroup, there were substantially more CSPCa, and also aggressive PCas than in men in the group with no MRI performed during the follow-up. The selection bias might have been affected by the result – a remaining clinical suspicion of a non-diagnosed aggressive PCa drives more easily to novel diagnostic methods.

In general, high-quality prospective, randomized studies had represented convincing results of prebiopsy MRIs high sensitivity to CSPCa in biopsy naïve patients. In PRECISION trial, the authors compared biopsy results in patient groups having SBs to a group having only multiparametric MRI TB: CSPCa was detected in 38% of men in a MRI-TB group, as compared with 26% of men in the standard-biopsy group [10]. In PROMIS trial, multiparametric MRI results compared to a standard TRUS protocol using transperineal template prostate mapping biopsies as a reference: sensitivity test for a CSPCa was 88% for a MRI, and 48% for standard TRUS biopsies [4]. These results are not only representing the superiority of MRI to detect CSPCa, but also a poor sensitivity of the traditional diagnostic protocol. Even if the study settings in the studies above vary from our study, the results are in line with ours.

Upgrading histologic and capsule invasive PCas in prostatectomy specimen was substantially and significantly more common in the non-MRI group. Again, differences between the study groups should be taken into

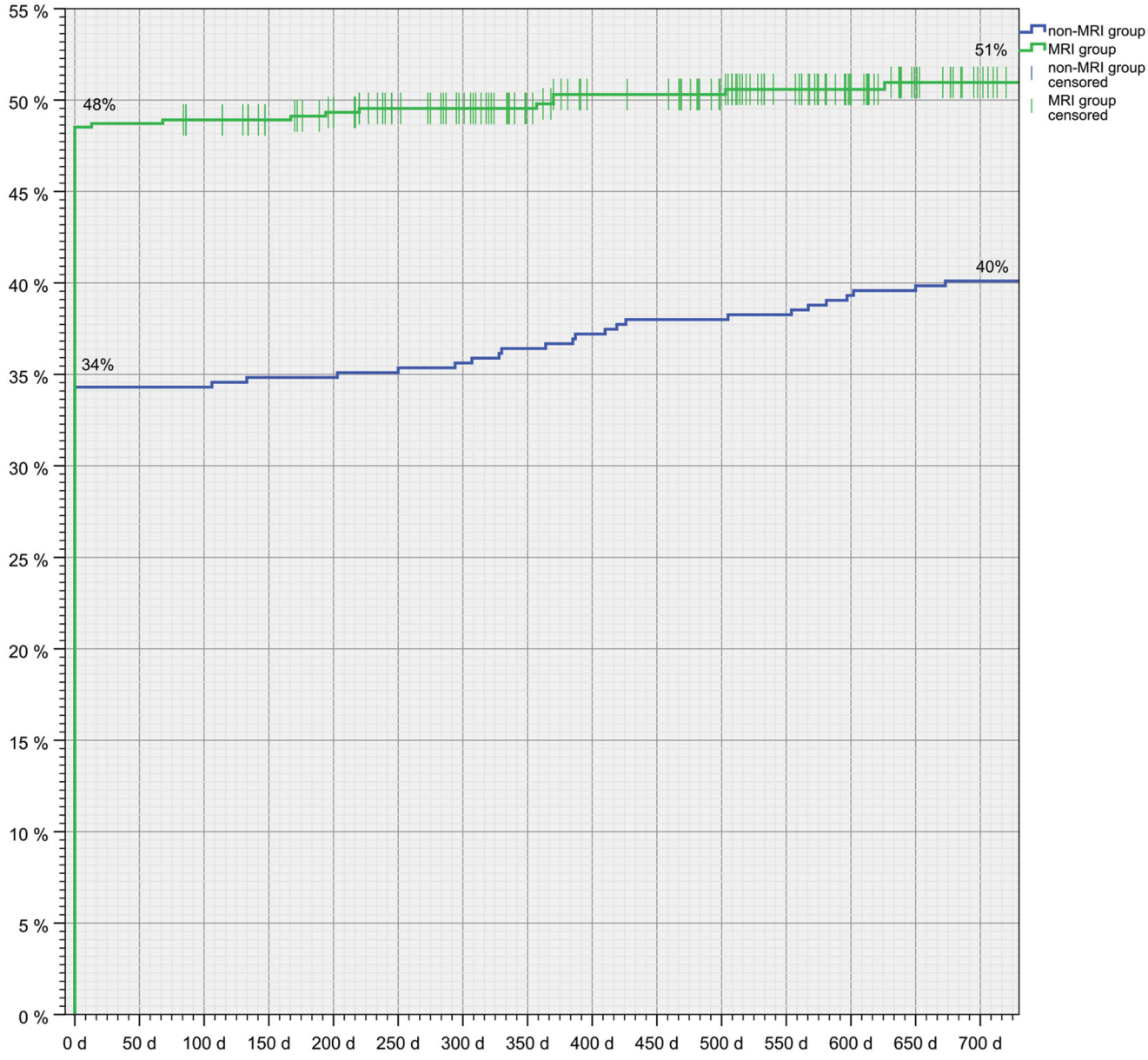

Figure 2. A Kaplan–Meier graph of a 2 years follow-up period of the study patients. The graph represents the prevalence of clinically significant prostate cancer (Gleason grade group 2 [Gleason score 3 + 4] or more malignant histology in any biopsy core taken) in the study groups during the first 2 years of follow-up.

account: prostatectomies were done more in the MRI group which might be explainable by younger mean age in the MRI group. However, the higher rate of men with PCa histology upgraded in prostatectomy, and also the lower rate of prostatectomies done in the non-MRI group, could be influenced by 'too bening' biopsy result, taking into account the lower rate of CSPCas diagnosed in the non-MRI group. Similar results are seen in other studies: Xu et al. retrospectively investigated prostatectomy specimens between patient groups having standard transrectal biopsies or transperineal multiparametric MRI TB [17]. In the study, upgrading histology in prostatectomy was in 26.9% of men in a prebiopsy MRI group and in 73.1% of men in a SB group [17]. Also Borkowetz et al. compared prostatectomy specimens in patient groups having standard TRUS guided biopsies with and without additional multiparametric MRI guided transperineal TBs [18]. In the study, a combination biopsy group and a SB group got upgrading histology in prostatectomy in 18% and 44% of cases, respectively [18].

In conclusion, the results of this study fortify the view that MRI with TBs gives a great additional value to SBs in the initial diagnostics of CSPCa, comparing it to the former initial diagnostic protocol which includes only SBs. It represented superiority with almost all the measured variables. Nevertheless, the combination gives no solution to an another diagnostic issue; diagnosing non-significant PCas, as seen also in this study: no difference seen in the rates of diagnosed GGG 1 PCas between the study groups.

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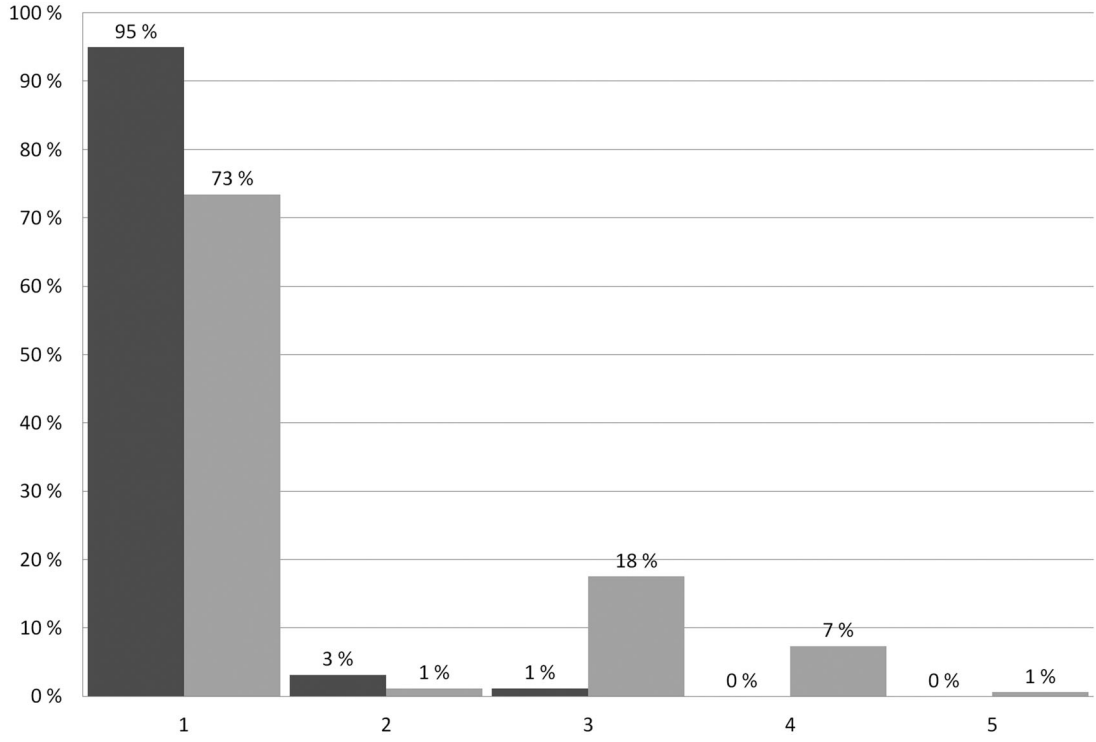

Figure 3. A graph representing how many biopsy sessions had to be performed for a diagnosis of a CSPCa during the follow-up. Dark grey bar represents the MRI group and light grey bar represents non-MRI group (control group). CSPCa: clinically significant prostate cancer (Gleason grade group 2 [Gleason score 3 + 4] or more malignant histology in any biopsy core taken); MRI: magnetic resonance imaging.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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