

Results of radical prostatectomy and short-term follow-up of men with ISUP GG 1 and 2 prostate cancer who underwent magnetic resonance imaging-guided active surveillance

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Introduction Multiparametric magnetic resonance imaging (mpMRI) reduces the need for repeat biopsies in prostate cancer (PC) patients under active surveillance (AS). The prospective PROMM-AS trial confirmed reliable prediction of upgrading in ISUP Grade Group (GG) 1–2 PC. We report outcomes of men from the PROMM-AS trial undergoing deferred radical prostatectomy (RP) after radiologic or histopathologic progression, including short-term oncological follow-up.

Material and methods The primary endpoint was biochemical recurrence (BCR; PSA ≥ 0.1 ng/ml). Secondary endpoints included adverse pathology (AP; ISUP GG ≥ 3 and/or $\geq pT3$ at RP), PSA level at 12 months, and metastases. Differences between ISUP GG were evaluated using Fisher's exact test. Sensitivity, specificity, positive and negative predictive value to predict BCR and AP were calculated. Regression analyses using MRI and clinical variables were performed to analyze predictors of BCR and AP.

Results Of 148 men, 28 (19%) – 10 GG1 and 18 GG2 – progressed (radiologic $n=15$, histopathologic $n=3$, combined $n=10$) and underwent RP within 24 months of trial duration. Median follow-up after RP was 24 months (IQR 15–38). Among 25 patients with ≥ 12 months follow-up, 92% achieved PSA < 0.01 ng/ml at 12 months. BCR occurred in 4 patients (14%), AP in 9 (32%), and 1 patient (3.6%) developed pelvic lymph node metastasis. Gleason Pattern (GP) 4 at biopsy, PI-RADS, and PRECISE scores significantly predicted BCR, while GP4 percentage, percentage of positive cores and PI-RADS predicted AP.

Conclusions These findings support the oncological safety of MRI-guided AS in terms of BCR and development of metastases in selected GG1/2 PC patients. However, the rate of AP needs to be acknowledged in patient counseling.

Key Words: active surveillance ◊ multiparametric MRI ◊ prostate cancer ◊ radical prostatectomy
◊ biochemical recurrence ◊ adverse pathology ◊ sensitivity and specificity

INTRODUCTION

Active surveillance (AS) is recommended for patients with low- or favourable intermediate-risk prostate cancer (PC), with long-term studies confirming its safety for cancer-specific survival [1–4]. Multiparametric magnetic resonance imaging (mpMRI) assists in patient selection and monitoring during AS, using PRECISE criteria to assess progression [5–8]. The PROMM-AS study is a prospective, single-arm phase 2 trial evaluating an MRI-based AS approach in men with low-risk ISUP Grade Group 1 (GG1) or favourable risk (GG2) PC. Study inclusion was based on baseline mpMRI followed by fusion biopsy (FBx), which comprised both targeted and systematic cores. In accordance with institutional practice, only men with at least one MRI-visible lesion scored Prostate Imaging–Reporting and Data System (PI-RADS) ≥ 3 underwent biopsy and were therefore eligible for inclusion. Follow-up mpMRI was performed at 12 and 24 months, and biopsies were deferred unless radiological progression (PRECISE score 4–5) or a PSA increase >0.75 ng/ml/year occurred. All patients underwent protocol-mandated mpMRI and MRI/TRUS-fusion biopsies at 24 months. PROMM-AS demonstrated that MRI-guided AS reduced the need for follow-up biopsies in 88% of GG1 patients and accurately predicted progression, as increased PRECISE scores predicted histological progression in 81% of GG1 and 92% of GG2 patients [9, 10].

This analysis presents outcomes of patients with deferred radical prostatectomy (RP) within PROMM-AS who discontinued AS after 24 months due to histopathological or radiological progression.

MATERIAL AND METHODS

All men who underwent RP within the PROMM-AS cohort were retrospectively analysed. Discontinuation of active surveillance and recommendation for radical prostatectomy were based on predefined radiological and/or histopathological progression criteria. Histopathological progression was defined as upgrading to ISUP Grade Group ≥ 2 in patients initially classified as Grade Group 1, or upgrading to ISUP Grade Group ≥ 3 in patients initially classified as Grade Group 2. Radiological progression was defined as a PRECISE score of 4 or 5 on follow-up multiparametric MRI, according to the PRECISE

reporting criteria [5, 6]. The primary endpoint was biochemical recurrence (BCR). Secondary endpoints included the occurrence of adverse pathology (AP; ISUP GG ≥ 3 and/or $\geq pT3$) at RP, prostate-specific antigen (PSA) at 12 months, and development of metastases.

Differences between ISUP GG groups were evaluated using Fisher's exact test. Sensitivity, specificity, positive and negative predictive value for initial PI-RADS and the PRECISE score on MRI to predict BCR and AP were calculated (Suppl. Table 1). Regression analyses using MRI and clinical variables predicted BCR and AP (Suppl. Table 2). Regression analyses incorporated clinical and MRI parameters with bootstrapping (1000 iterations). Continuous variables were modelled nonparametrically with cubic splines or transformations (log transformation, polynomials). To account for nonlinearity between PRECISE categories (1–3 and 4–5), PRECISE and PI-RADS scores were modelled with cubic splines. All tests were two-sided with a 5% significance level. Statistical analyses were performed using PRISM 9.4.1 (GraphPad, San Diego, USA) and SPSS 30.0 (IBM, Armonk, USA). Analyses followed STARD criteria for reporting diagnostic accuracy (Suppl. Table 3) [11]. All MR examinations were prospectively evaluated by or under the supervision of a board-certified radiologist (LS) with over 10-year experience in reading prostate MRI (1000 scans per year). Histological tissue samples were examined according to ISUP guidelines by or under supervision of two experienced uropathologists (with more than 10 years' experience in prostate pathology, TR and IE).

Bioethical standards

The PROMM-AS study was approved by the local ethics committee of the Heinrich-Heine University Dusseldorf (ID 2017034168), and written informed consent was obtained from all participants prior to study inclusion.

RESULTS

Of 148 men, 41 (27%; 22 ISUP GG1, 19 ISUP GG2) discontinued AS in the 2-year study period; 33 underwent RP, 5 of those discontinued voluntarily, 8 received other treatments (CONSORT flow chart and details in Suppl. Figure 1, Suppl. Table 4).

Among the 28 evaluable RP patients, 3 (11%) discontinued due to histopathological progression alone, 15 (54%) due to radiological progression, and 10 (36%) due to both. ISUP GG ≥ 3 at RP was observed in total in 25% of patients, in 10% of ISUP GG1 and 33% of ISUP GG2 patients ($p = 0.36$, CI: from -0.52 to 0.05). AP was found in 32% (2 ISUP GG1 and 7 ISUP GG2 cases, $p = 0.31$, CI: from -0.17 to 0.45). The distribution of ISUP grade and pT-stage is summarized in Table 1B. Median follow-up was 24 months after RP. Following RP, all patients achieved PSA <0.01 ng/ml, with 92% of them maintaining this at 12 months. Four men (14%) developed BCR during follow-up, and one patient developed pelvic lymph node metastasis, detected using prostate-specific membrane antigen (PSMA) positron emission tomography (PET) computed tomography (CT). In particular out of the 9 patients with AP, only one patient had AP and positive surgical margins (PSM), whereas 5 patients had PSM without AP. When these data are correlated with the four men suffering from BCR, only one man had PSM (and AP) and BCR. The PRECISE score had high sensitivity (0.84) to predict and rule out (negative predictive value, NPV, 0.86) AP. However, whereas NPV for ruling out BCR was high (0.84), sensitivity was limited (0.67). This was also the case for initial PI-RADS scoring for both, AP and BCR (Suppl. Figure 1). Regression analyses (Suppl. Table 2) identified the percentage of Gleason pattern 4 (GP4) ($p = 0.01$), initial PI-RADS score ($p = 0.03$), initial PSA (0.03) and PRECISE score ($p = 0.02$) to predict BCR. The percentage of GP4 ($p = 0.02$), percentage of positive cores ($p = 0.01$), and initial PI-RADS score ($p = 0.01$) were significant predictors of AP. Due to few metastases, no regression analysis was performed for metastasis prediction.

DISCUSSION

This evaluation of RP specimens and short-term follow-up demonstrated that an MRI-guided AS protocol like PROMM-AS is oncologically safe in ISUP GG1/2 PC and can aid personalized AS follow-up as recently proposed [11].

AP was observed in 32% of cases. Although higher among men with initial ISUP GG2 PC (39% vs 20%), the difference vs ISUP GG1 was not statistically significant; however, the number of ISUP GG1 cases was low. The AP rate in ISUP GG2 patients (39%) was comparable to the University of California, San Francisco (UCSF) cohort (38%) or to the multicenter cohort by Baboudjian (46%) [12, 13]. The AP rate in ISUP GG1 (20%) matched findings from the PRIAS study [14]. Notably, none of the patients

Table 1. A) With descriptive statistics of the cohort, **B)** with results of radical prostatectomy and follow-up

A. Descriptive statistics	
Parameter	
Number of men included into study	28
Median Age, years (yr) [IQR]	59 [51; 67]
Median pre-biopsy PSA-level ng/ml [IQR]	5.9 [3.9; 8.2]
Suspicious DRE findings (cT2a), n (%)	5 (15)
Median prostate volume, ml [IQR]	30 [25; 49]
Median PSA density $\pm$ IQR	0.15 [0.11; 0.25]
Number of patients with initial MRI score PIRADS 3 (%)	12 (42)
Number of patients with initial MRI score PIRADS 4 (%)	8 (29)
Number of patients with initial MRI score PIRADS 5 (%)	8 (29)
Biopsies per patient, median [IQR]	16 [14; 18]
Men with cribriform pattern, n (%)	0
Men with initial ISUP GG 1 PC at AS inclusion, n (%)	10 (36)
Men with initial ISUP GG 2 PC at AS inclusion, n (%)	18 (64)
Median percentage of GP 4 in ISUP GG 2 PC subgroup, n	20 [20; 30]
Median time to RP, months [IQR]	12 [10; 24]
B. Radical prostatectomy specimen and follow-up	
Parameter	
Patients with pT2 stage, n (% of all men)	22 (79)
Patients with pT3 stage, n (% of all men)	6 (21)
Patients with pT2 stage in initial ISUP GG 1, n (% of all men)	8 (80)
Patients with pT3 stage in initial ISUP GG 1, n (% of all men)	2 (20)
Patients with pT2 stage in initial ISUP GG 2, n (% of all men)	14 (77)
Patients with pT3 stage in initial ISUP GG 2, n (% of all men)	4 (23)
ISUP GG 1 at RP, n (% of all men)	0 (0)
ISUP GG 2 at RP, n (% of all men)	21 (75)
ISUP GG 3 at RP, n (% of all men)	4 (14)
ISUP GG 5 at RP, n (% of all men)	3 (11)
Resection margin status RO (%), R1 (%)	22 (79), 6 (21)
Adverse pathology, n (%)	9 (32)
Adverse pathology in initial ISUP GG 1, n (% of men with initial ISUP GG 1 PC)	2 (20)
Adverse pathology in initial ISUP GG2, n (% of men with initial ISUP GG 2 PC)	7 (39)
Patients with PSA response, n (%)	28 (100)
Patients with PSA response after 12 months, n (% of all 25 men with 12 month-FU)	23 (92)
Patients with biochemical recurrence BCR, n (% of all 28 men)	4 (14)
Median time to BCR, months [IQR]	22 [15; 38]
Patients with development of metastasis, n (%)	1 (3.6)
Median time to metastasis, months [IQR]	24 [15; 38]

BCR – biochemical recurrence; IQR – Inter Quartile Range; PSA – prostate-specific antigen

undergoing deferred radical prostatectomy had ISUP Grade Group 1 disease at final pathology, supporting an association between radiological progression during active surveillance and the presence of higher-grade disease. Initial PI-RADS score was a significant predictor of AP. In this context, our findings align with Gallagher, who showed moderate-risk MRI findings were associated with low AS disqualification rates, although PI-RADS scoring was not applied [15]. Only patients with ≥ 1 PI-RADS ≥ 3 lesion underwent MRI/transrectal ultrasound (TRUS) fusion biopsy and were included in PROMM-AS. This preselection likely introduced a selection bias toward higher-risk patients and may partly explain the relatively high discontinuation rate and AP occurrence of 32%, compared to other contemporary cohorts [16].

The PRECISE score was not a significant predictor in regression analysis, but its NPV for excluding BCR and AP remained high (86%). Of note, also the sensitivity of the PRECISE score for AP was high (0.84). After RP, all men achieved a PSA response < 0.01 ng/ml, with 14% developing BCR and 3.6% developing regional metastases at a median follow-up of 24 months. All men with BCR had an initial GP4 $\geq 20\%$, and GP4 was a significant predictor of BCR in regression analysis. These findings are consistent with those reported by Sauter regarding GP4 percentage predicting BCR but somewhat contrary to Uleri, who did not find a significant correlation to ISUP GG3 upgrading or definitive treatment [17, 18].

Importantly, the metastasis rate observed (3.6%) was comparable to recent AS studies despite their longer follow-up durations [12, 13, 19]. Given the limited sample size ($n = 148$) and relatively short median follow-up (24 months), longer observation is needed to confirm long-term oncological safety. Notably, men who discontinued AS without undergoing RP ($n = 8$) were not excluded from the primary safety evaluation and will be included in long-term oncological outcome analysis.

The limitations of this study include the short follow-up and the small sample size inherent to this prospective trial. Additionally, the disqualification rate of 27% likely reflects inclusion of only patients with PI-RADS ≥ 3 lesions. Importantly, given the very limited number of oncological events, the results of the multivariable regression analyses must be regarded as exploratory, statistically underpowered, and hypothesis-generating, and therefore require validation in larger, independent cohorts.

In future studies, outcomes will be analysed on an intention-to-treat basis to provide a more comprehensive assessment of MRI-based AS protocols and support their broader adoption in clinical practice.

CONCLUSIONS

In conclusion, PROMM-AS shows that an mpMRI-guided AS protocol is oncologically safe in the short term for men with ISUP GG1–2 prostate cancer, with respect to biochemical recurrence and metastatic progression. Predictors of AP included positive cores, GP4 percentage, and initial PI-RADS score and PRECISE scoring on MRI has both high sensitivity and NPV, supporting MRI-based personalized AS strategies, like proposed in STRATCANS. However, the rate of AP (32%) needs to be acknowledged in patient counseling.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

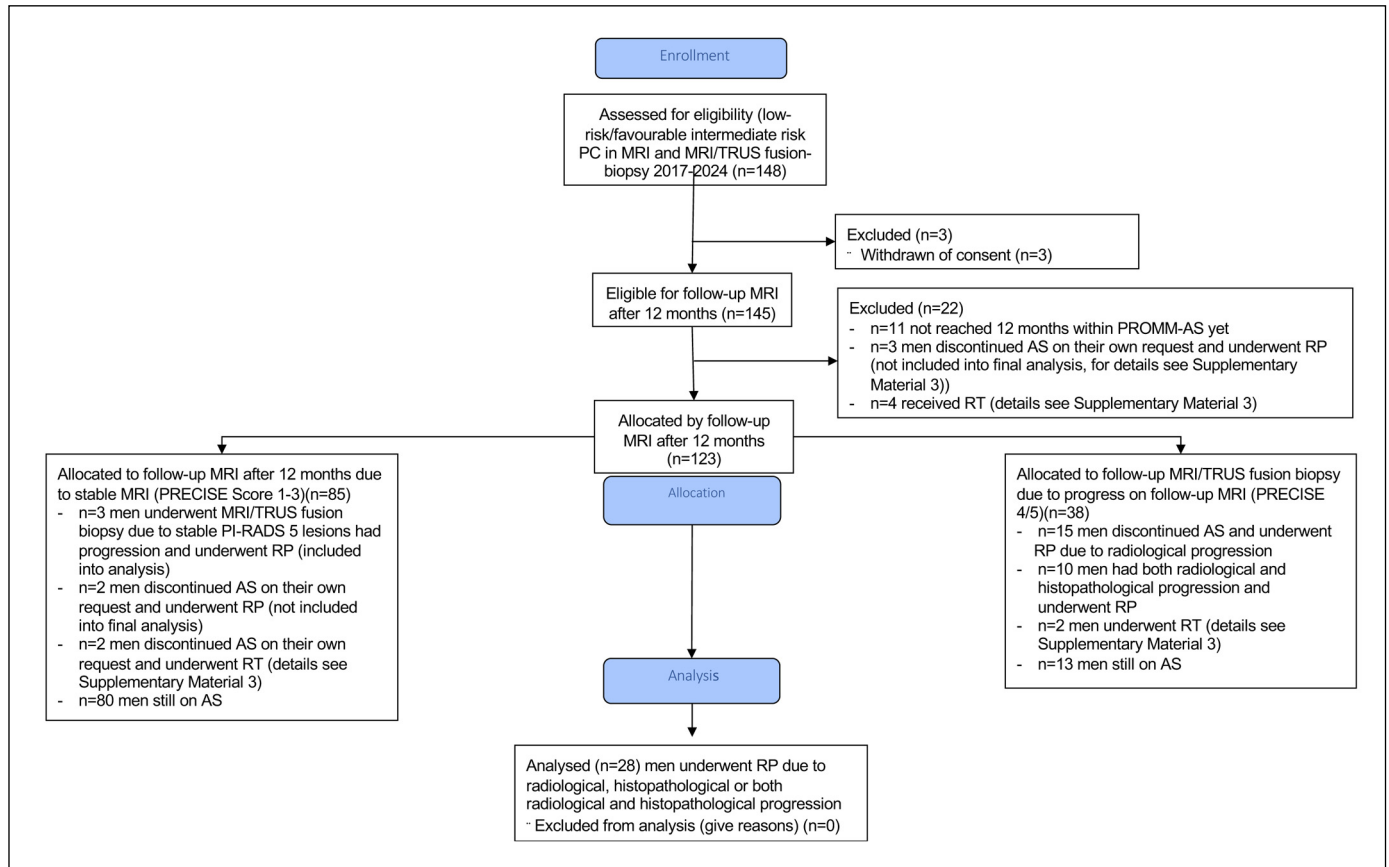
FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The PROMM-AS study was approved by the local ethics committee of the Heinrich-Heine University Dusseldorf (ID 2017034168), and written informed consent was obtained from all participants prior to study inclusion.

SUPPLEMENTARY MATERIALS



Suppl. Figure 1. CONSORT flow chart.

Suppl. Table 1. Sensitivity, specificity, positive and negative predictive value of PI-RADS and PRECISE Score to determine BCR and AP at radical prostatectomy specimen

Test	Sensitivity	Specificity	PPV	NPV
PI-RADS Score to predict BCR, 95% CI	0.33 (0.06–0.79)	0.84 (0.65–0.94)	0.20 (0.04–0.62)	0.91 (0.73–0.98)
PI-RADS Score to predict AP, 95% CI	0.21 (0.05–0.56)	0.81 (0.60–0.93)	0.20 (0.05–0.59)	0.78 (0.58–0.90)
PRECISE Score to predict BCR, 95% CI	0.67 (0.21–0.94)	0.24 (0.12–0.43)	0.10 (0.03–0.29)	0.86 (0.54–0.976)
PRECISE Score to predict AP, 95% CI	0.84 (0.65–0.96)	0.8 (0.15–0.48)	0.26 (0.12–0.46)	0.86 (0.54–0.96)

AP – adverse pathology; BCR – biochemical recurrence; CI – confidence interval; NPV – negative predictive value; PPV – positive predictive value; PI-RADS – Prostate Imaging–Reporting and Data System

Suppl. Table 2. A) Regression analysis of parameters to predict adverse pathology at radical prostatectomy and **B)** regression analysis of parameters to predict biochemical recurrence in the short-term follow-up after radical prostatectomy

A. Regression analysis using cubic splines and polynomes for prediction of AP				B. Regression analysis using cubic splines and polynomes for prediction of BCR			
Parameter	Odds ratio	95% CI	P value	Parameter	Odds ratio	95% CI	P value
Age, per 5 years	1.03	−2.70–13.71	0.51	Age, per 5 years	1.08	0.36–2.96	0.19
Initial PSA	1.02	−20.03–11.98	0.75	Initial PSA	1.53	1.06–2.29	0.03
Initial PSA density	1.47	0.97–1.56	0.29	Initial PSA density	0.99	0.88–1.45	0.07
PSA kinetic (PSA >0.75/a)	1.02	−1.16–1.26	0.41	PSA kinetic (PSA >0.75/a)	1.00	−1.44–1.34	0.61
Initial ISUP Grade group 1 vs 2	−2.40	−9.17–17.56	0.18	Initial ISUP Grade group 1 vs 2	−1.73	−2.63–2.49	0.16
Gleason Pattern 4 in %, per 10%	1.17	1.07–1.55	0.02	Gleason Pattern 4 in %, per 10%	1.10	1.02–1.90	0.01
Percentage of positive Core Involvement, per 10%	1.16	1.08–1.48	0.01	Percentage of positive Core Involvement, per 10%	1.02	0.83–2.04	0.24
Initial PI-RADS Score, per Score	1.31	1.15–1.54	0.01	Initial PI-RADS Score, per Score	1.75	1.32–3.36	0.03
PRECISE Score, per Score	1.66	0.92–2.05	0.08	PRECISE Score, per Score	2.35	1.20–6.73	0.02

PI-RADS – Prostate Imaging–Reporting and Data System; PSA – prostate-specific antigen

Suppl. Table 3. STARD checklist for reporting of studies of diagnostic accuracy

Section and Topic	Item #		On page #
TITLE/ABSTRACT/KEYWORDS	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').	269
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.	270
METHODS			
Participants	3	The study population: The inclusion and exclusion criteria, setting and locations where data were collected.	270, 271, Table 1
	4	Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	270
	5	Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.	270
	6	Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	270
Test methods	7	The reference standard and its rationale.	270
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	270
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	270
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	270
Statistical methods	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	270
	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	270
	13	Methods for calculating test reproducibility, if done.	270
RESULTS			
Participants	14	When study was performed, including beginning and end dates of recruitment.	270, Table 1
	15	Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).	270, Table 1
	16	The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).	270, Table 1, Suppl. Tables 1, 3

Section and Topic	Item #		On page #
Test results	17	Time-interval between the index tests and the reference standard, and any treatment administered in between.	Table 1
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	270, Table 1
	19	A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	Suppl. Figure 1, Suppl. Table 3
	20	Any adverse events from performing the index tests or the reference standard.	N/A
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	271
	22	How indeterminate results, missing data and outliers of the index tests were handled.	271
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	N/A
	24	Estimates of test reproducibility, if done.	271
DISCUSSION	25	Discuss the clinical applicability of the study findings.	271, 272

[illegible]

Suppl. Table 4. Continued

Subject	1	2	3	4	5	6	7	8	9	10	11	12	13
PI-RADS of serial MRI after 12 months	4	3	4	4	4					5	4	4	4
PRECISE Score	4	3	4	2						5	3	3	3
MRI/TRUS-Fusion biopsy after 12 months										ISUP GG 2	ISUP GG 2		
Treatment	RP on own request	RP on own request	RP on own request	RP on own request	RP on own request	RT	RT	RT	RT	RT	RT	RT	RT
Pathology	pT2a pN0 LO VO RO ISUP GG 2	pT2a pN0(0/41) LO VO Pn0 ISUP GG 2	pT2c pN0(0/19) LO VO Pn1 R1 ISUP GG 2	pT2a pN0 (0/4) LO VO RO ISUP GG 2	pT2c pN0 (0/15) LO VO Pn1 RO ISUP GG 3								
pN	0	0	0	0	0								
R-Status	0	0	1	0	0								
RP ISUP GG	2	2	2	1	3								
EPE	0	0	0	0	0								
AP	0	0	0	0	1								
PSA response	4	3	4	4	4	1	1	1	1	1	1	1	1
PSA response 12 m	3	3	3	3	3	1	1	1	1	1	1	1	1
BCR	No	No	No	No	No	No	No	No	No	Yes	No	No	No
Last PSA	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.53	<0.01	<0.01	<0.01
Last MET status	0	0	0	0	0	0	0	0	0	0	0	0	0
Month after therapy at last status	56	40	33	43	14	27	28	66	71	48	76	53	51

AP – adverse pathology; BCR – biochemical recurrence; CI – confidence interval; MRI – magnetic resonance imaging; PSA – prostate-specific antigen

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